REPORT OF THE INTERAGENCY JOINT LABOR/MANAGEMENT COMMITTEE ON PRESCRIPTION DRUGS FROM CANADA

April 2004

1. Background

On November 4, 2003 the Montgomery County Council approved Resolution No. 15-385 on securing lower-price prescription drugs for current and retired employees of County agencies. (See circles 1-2.) The resolution discussed the impact of the soaring price of prescription drugs and the arguments for and against enabling active employees and retirees to obtain these drugs from Canada. The Canadian government sets price controls for prescription drugs that makes them significantly cheaper than the same drugs in the U.S. The resolution further called on the Task Force on Health Benefits Improvements, created on April 29, 2003 by then-Council President Michael Subin and chaired by Wendell M. Holloway, to examine this issue and report to the Council and the Management and Fiscal Policy Committee.

The Holloway Task Force, in its report to the Council dated November 25, 2003, proposed the creation of an interagency joint labor/management committee to pursue this effort. The report language, including the proposed charge to the Committee, is on circles 3-4.

The Committee, composed chiefly of County agency benefits experts and union representatives, was convened by Council Vice President Tom Perez. The committee met on January 9 and 21, February 4 and 19, and March 25, 2004.

The agency benefits experts – who provided valuable data and insights but are not the policy-makers for their agencies – were Wes Girling (MCPS), Eric Wallmark (County Government), Jan Lahr-Prock (M-NCPPC), Lynda von Bargen and Karen Bass (Montgomery College), and Mike Glass and Karen Gerald (WSSC). The union representatives on the committee were Gino Renne and Robert Stewart (MCGEO/UFCW Local 1994), Tom Israel (MCEA), Dave Rodich (SEIU Local 500), John Sparks (IAFF Local 1664), and Walt Bader (FOP Lodge 35). Other participants were: Chuck Milligan, Vice President of the Lewin Group and former New Mexico Medicaid Director; currently Executive Director of the Center for Health Planning, Development and Management, at the University of Maryland, Baltimore County; Wayne Sauseda, Chair of the Commission on Health; and the Confidential Aides of several Councilmembers.

It is important to note that the agreements that have been negotiated recently with MCEA, SEIU, MCGEO, and FOP all contain language that would allow the inclusion of a Canadian drug importation program as part of the prescription benefits package.

To conduct its review the Committee examined extensive information on prescription drugs from Canada, including actions taken or contemplated by states and localities elsewhere, statements by the Food and Drug Administration, and the perspectives of such groups as the Biotechnology Industry Organization and the BioAlliance. All Councilmembers received the Committee's extensive packet of background information dated January 7.

It is important to outline the scope of a potential importation program. The Committee has been studying the feasibility of allowing current and retired employees to import certain maintenance drugs for personal use. Maintenance drugs are medications that people for use for long periods of time, such as cholesterol and high blood pressure drugs. Acute care needs and short-term medications would continue to be met at local pharmacies.

The Committee focused on three questions about possible drug importation from Canada:

- Is it safe?
- Is it legal?
- Is it cost-effective?

To help answer these questions, the Committee convened a public forum on February 23. The forum, moderated by Mr. Perez, featured an overview by the benefits experts of prescription drug costs for both agencies and employees; an expert panel with diverse perspectives on the safety, legal, and cost issues; and a panel of employees with concerns about prescription drugs. Testimony offered at the forum is posted on the Council's web site. Panel members included:

John Rich, M.D., Medical Director, Boston Public Health Commission
William Hubbard, Senior Associate Commissioner, FDA
Dr. John Holaday, Chairman, Maryland BioAlliance
David Nexon, Senior Health Advisor to Sen. Edward Kennedy, Minority Staff Director for Health Policy for the Senate Committee on Health, Education, Labor and Pensions
Stan Gordon, Second Vice-President, Maryland-D.C Chapter of the Alliance for Retired Americans
G. Anthony Howard, President, CanaRx Services, Inc. Windsor, Ontario
Charles Milligan, J.D., M.P.H., then Vice-President, Lewin Group.

The Committee also developed a survey instrument to which nearly 400 agency employees have already responded. One purpose of the survey was to gauge employee interest in a drug importation program. The initial response to the Committee's survey [396 employees] indicates that 68% of respondents would use the service, 10% would not because they do not use maintenance drugs, and 20% would not use the service. More than 70% of respondents indicated that they believe the County should offer a Canadian mail order option. The full survey is at circles 5-8. When further responses are in hand, the results will be assessed and reported to the Management and Fiscal Policy Committee.

2. Prescription Drug Costs for Montgomery County

The benefits experts' presentation at the Committee's February 23 public forum provided valuable information about prescription drugs costs for the five County and bi-County agencies and their employees. (See circles 9-19.)

More than 40,000 active and retired employees, and their more than 45,000 qualified dependents, receive health benefits. Agencies and employees combined spent more than $330 million for these benefits in 2003. Of this total, prescription drugs cost an estimated $70 million.

Specific data on prescription drug costs is sometimes difficult to extract, particularly when drug coverage is not stand-alone – as, for example, in the Kaiser plan. MCPS and M-NCPPC provide stand-alone programs where the cost is more easily captured.

MCPS' experience is representative of all agencies' experience. Between 1997 and 2003:

• Prescription drug costs more than doubled for active employees (from $883 to $1,992) and nearly doubled for retirees (from $1,513 to $2,913).

• The average net drug cost per script rose sharply for both active employees (from $37.68 to $71.09) and retirees (from $47.24 to $67.15).

• The average number of scripts rose, although somewhat less sharply, for both active employees (from 23.4 to 28.0) and retirees (from 32.0 to 43.4).

These statistics are consistent with the national trends. Families USA, a group that tracks healthcare issues for consumers, reports that the prices for the 50 top selling drugs have increased at rates that are 'significant multiples of inflation' for more than a decade. "From January 2002 to January 2003, for example, the prices of those top 50 drugs rose by almost three-and-one-half times the rate of inflation."

[http://www.familiesusa.org/site/PageServer?pagename=medicare_drug_discount_card]

3. Other Jurisdictions with Current or Potential Prescription Drug Importation Programs

The number of states and localities that have expressed interest in importation programs has grown rapidly over the last year, and the landscape continues to change rapidly. **Springfield, Massachusetts** and **Montgomery, Alabama** actually started limited programs for their employees and retirees in 2003. Springfield raised co-payments for domestic drugs and waived them for imported drugs. The results from December 2003, shown on circle 20, indicate that 31% of the 10,031 eligible employees have enrolled. Savings on 2,434 prescriptions issued in December were $243,605 or 40.7%. A column on circles 21-23 by former Mayor Michael Albano, who started the program, provides further details. **Boston**, whose Medical Director participated in the Committee's February 23 public forum, is carefully planning to implement a program later this year. The following cities have requested proposals for a program from the same Canadian pharmacy benefits manager as Springfield: New Castle, DE; Fort Wayne, IN; Seattle, WA; Quincy, MA; and Schenectady, NY.

Many states have expressed interest. **Illinois** issued an extensive report in October 2003 that posited large savings, but when the federal waiver it requested to implement the program was not granted, it did not proceed. **Vermont** has also sought a federal waiver.

Other states have taken more direct action. **Minnesota** has a website that lists pharmacies that the state has inspected and certified. **Wisconsin** has created a web site linking residents to Canadian pharmacies that provide specific safeguards. Pages from these websites start at circle 24. **New Hampshire** has created a similar website but has not taken it live at this time. **Iowa** and **West Virginia** are among the other states contemplating action. There is a bill pending in the Maryland Senate that would allow importation of Canadian drugs for state employees.

4. Federal Political Context

Before reviewing the key safety, legal, and cost issues associated with drug importation, we believe that a sense of the federal political context would be useful. Part of this context is the debate between the FDA and its critics over legal issues, which are discussed below. Another part is the growing bipartisan focus on this issue in Congress, parallel to the state and local focus.

In September 2003 the House of Representatives, by a vote of 243-186, approved legislation directing the Department of Health and Human Services to establish a system for importation of FDA-approved drugs from FDA-approved facilities in Canada, the European Union, and seven other nations. A bipartisan group of Senators introduced a similar bill in the Senate, but the final Medicare prescription drug bill in late 2003 included a much more limited provision on drug importation, as noted below.

So far in 2004, the landscape has continued to change. AARP, which helped to pass the Medicare prescription drug bill, has intensified its support for importation. While there remains opposition to importation, some former opponents, such as Republican Senators Trent Lott and John Cornyn, have recently changed their position to support it, as Senator Edward Kennedy and others did last year.

Recently Senators John McCain and Byron Dorgan temporarily held up the nomination of FDA Commissioner Mark McClellan to head the Medicare and Medicated programs because of his position on importation. Senator William Frist has agreed to allow a drug importation bill to come to a vote in the Senate this year. Passage of the measure now appears likely in the Senate, although whether it will become law again remains far from certain.

5. Safety Issues

The primary goal of Montgomery County's employee health benefits programs is the well-being of participants. Any prescription drug program must ensure safe and easy access to the drugs prescribed by an employee/retiree's physician. The key question is: can one design a safe and reliable program for importing drugs from Canada?

The Committee spent considerable time addressing this issue and reviewed a host of documents and reports. It received technical assistance from a high ranking official from the Lewin Group (a national healthcare consulting firm). It received testimony from a variety of witnesses at the public forum, including a senior associate commissioner from FDA and the medical director for Boston's public health system. The Committee also met with the senior management team of the Canadian company that is working with Springfield, Massachusetts and other government entities to implement these programs.

A. Conflicting Stands

The Food and Drug Administration maintains that it is unsafe to import drugs from Canada or any other country. In testimony before the Committee on Government Reform's Subcommittee on Human Rights and Wellness (June 12, 2003), Senior Associate Commissioner William K. Hubbard, stated the Administration's position on the safety of importing prescription drugs from Canada:

> For public health reasons, FDA remains concerned about the importation of prescription drugs into the U.S. In our experience, many drugs obtained from foreign sources that either purport to be or appear to be the same as U.S.-approved prescription drugs are, in fact, of unknown quality. FDA cannot assure the American public that drugs imported from foreign countries are the same as products approved by FDA.
>
> FDA has long taken the position that consumers are exposed to a number of risks when they purchase drugs from foreign sources or from sources that are not operated by pharmacies licensed under state pharmacy law.

In response to a question by Rep. Dan Burton (R-IN) at the same hearing, Commissioner Hubbard stated that FDA has no record of any harm to any person who has imported drugs from Canada. IMS Health, Inc., which tracks prescriptions for the health industry, estimates that more than 1 million United States residents buy drugs from Canada and have been doing so for years. The Governor of Wisconsin has estimated that 2 million Americans are buying drugs from Canada. Testimony at the Committee's public forum noted that 8 million prescriptions were filled in Canada for Americans in 2003. The FDA has not provided any incident of an American consumer being harmed by prescription drugs from Canada.

The City of Springfield, Massachusetts has had a Canadian drug importation program for employees in place since July 2003. The program is voluntary, and approximately one-third of eligible employees (3,112) have enrolled. They order their maintenance drugs from CanaRx, Inc. and the City pays the bill as part of the employee benefits package. CanaRx, Inc. is a pharmacy benefits manager (PBM) that contracts with Canadian pharmacies to fill prescriptions written in the USA. The City does not import, order, or possess the drugs at any point in the process. A description of the process is on circles 29 and 30. In December 2003, 2,434 prescriptions were filled at a 40% savings

($243,605) when compared to retail pharmacy costs in the USA. After six months there are no reports of any safety problems for Springfield employees.

B. Can We Design a Safe Importation Program?

Numerous organizations have concluded that importation programs can be safely designed. The U.S. Congress has passed laws (e.g., MEDS Act of 2000, Medicare Modernization Act of 2003) establishing guidelines for creating safe importation programs.

A major report by the State of Illinois concluded last year that:

- Employees and retirees can purchase safe and lower cost drugs from Canada.
- Pharmacy practice in Canada is equal or superior to the pharmacy practice in the State of Illinois
- Several features of the proposed plan designs for State of Illinois employees and retirees could encourage increased patient safety...
- The Canadian regulatory system provides substantially equivalent protection for the health and safety of the public as is provided in the State of Illinois. While there are differences in details of how the pharmacy profession is regulated, the standards of safety and efficacy of prescription drugs are comparable.
- Currently the Canadian system for pricing and distribution of pharmaceuticals is less likely than that of the system in the United States to foster drug counterfeiting...
- The United States and Canada have comparable requirements at virtually every level for the warehousing and storage of pharmaceuticals.

> Report On Feasibility of Employees and Retirees Purchasing Prescription Drugs in Canada, Oct. 27, 2003, Illinois Department of Central Management Services http://www.affordabledrugs.il.gov/pdf/SpecialAdvocateCanadian10-27-03Final.pdf

Charles Milligan, Vice-President of the Lewin Group and former Medicaid Director for New Mexico, reported to the Committee that in his judgment it is possible to design a safe program for importing drugs from Canada (circle 31-34). Mr. Milligan noted that it would be important to conduct a significant amount of due diligence before putting a program in place. He outlined a series of measures that he believes would ensure the safety of any program, and noted that they would be consistent with all of the Canadian drug reimportation guidelines signed into law by President Bush in December 2003 as part of the Medicare Modernization Act (H.R.1). These safety measures are:

- Only FDA-approved medications;
- Maximum 90-day supply of any given medication (to discourage re-sale, and allow for regular monitoring);
- Prohibit importation for the "first fill" of any given medication (to establish it is effective and tolerated by the patient);

- Permit importation only of County-designated maintenance medications for chronic conditions;
- The prescription must be written by the participant's local treating physician;
- The County should carefully select the approved Canadian vendor(s) according to criteria such as on-site physicians, 24 hour call center staff, and a record of compliance with all Canadian licensure laws;
- The Canadian vendor(s) must register with the Secretary of the federal Department of Health and Human Services ("HHS");
- The prescription must be for personal use by the County plan participant, and not for resale; and
- The prescription must be in the form of a final finished dosage that was manufactured in an establishment registered with the FDA.

The Committee continues to search for evidence that Americans who import prescription drugs from Canada, or Canadians who purchase prescription drugs, have encountered safety problems. It appears that the widespread practice of importing prescription drugs from Canada that currently exists has created no significant public health problem in America.

In the public forum, Dr. John Holaday, Chairman of the Maryland BioAlliance, raised a number of specific safety concerns pertaining to importation of biotech drugs. The Committee agrees that biomeds, because of their unique properties and storage requirements, present particular concerns, and that it would be inappropriate to permit importation of biomeds. Thus, if the County were to adopt a drug importation program, the Committee recommends that biomeds not be included in the list of maintenance drugs eligible to be purchased from Canada.

6. Legal Issues

There are two legal questions surrounding the drug importation proposal. First, does it violate federal law, specifically, the Food, Drug and Cosmetic Act? Second, what are the tort liability implications for the County?

A. Does the Proposed Drug Importation Proposal Violate Federal Law?

There is considerable disagreement as to whether a voluntary drug importation program would violate federal law. The FDA says unequivocally that such programs violate the Food, Drug and Cosmetic Act. (FDCA). In an August 25, 2003 letter to the Attorney General of California (http://www.fda.gov/opacom/gonot.html), the FDA opined that:

> ...virtually all drugs imported to the United States from Canada violate the FDCA because they are unapproved (21 U.S.C. § 355), labeled incorrectly (21 U.S.C. §§ 352, 353), or dispensed without a valid prescription (21 U.S.C. § 353(b)(1)). Importing a

> drug into the United States that is unapproved and/or does not comply with the labeling requirements in the FDCA is prohibited under 21 U.S.C. §§ 331(a), and/or (d).
>
> FDA approvals are manufacturer-specific, product-specific, and include many requirements relating to the product, such as manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance. 21 C.F.R. § 314.50. Generally, drugs sold outside of the United States are not manufactured by a firm that has FDA approval for that drug. Moreover, even if the manufacturer has FDA approval for a drug, the version produced for foreign markets usually does not meet all of the requirements of the United States approval, and thus it is considered to be unapproved. 21 U.S.C. § 355. The version also may be misbranded because it may lack certain information that is required under 21 U.S.C. §§ 352 or 352(b)(2) but is not required in the foreign country, or it may be labeled in a language other than English (see 21 C.F.R. § 201.15(c)).
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> Second, with respect to "American goods returned," it is illegal for any person other than the original manufacturer of a drug to import into the United States a prescription drug that was originally manufactured in the United States and sent abroad (21 U.S.C. § 381(d)(1)). This is true even if the drug at issue were to comply in all other respects with the FDCA. Id. Importing a drug into the United States in violation of section 381(d)(1) is prohibited under 21 U.S.C. § 331(t).

There is an opinion from an Assistant Attorney General of Maryland agreeing with the FDA's analysis. (See circles 35-39).

However, there are others who disagree with the FDA's analysis. The Attorney General of Minnesota has concluded that it is possible to implement a drug importation program without running afoul of the FDCA. In a letter dated October 2, 2003, the Attorney General made the following statements:

> Under current law, the federal Food, Drug and Cosmetic Act prohibits the importation of drugs into the United States from Canada by anyone other than a drug manufacturer if the drugs were manufactured in the United States. See 21 USC 381(d)(1). This provision of the law has been tempered by the FDA's longstanding practice of allowing consumers to import small amounts of prescription drugs for their own personal use. Additionally, Section 381(d)'s prohibition may be lifted if the Secretary of Health and Human Services certifies the safety of such drugs being imported. See 21 U.S.C. 384(l). To date, the Secretary has refused to do so even though drugs have been imported from Canada for years and the FDA

> has acknowledged that there have been no or negligible safety problems associated with these imported drugs....
>
> There is, on the other hand, no legal prohibition on the importation of drugs from Canada which are manufactured in other countries if the drugs are FDA approved, properly labeled and prescribed by a physician. See 21 U.S.C. 353, 355. *Accordingly, it is our opinion, that under current law, the State could implement a program regarding those medications either by buying direct or by establishing a conduit through which Medicaid recipients could purchase such medication.* [Emphasis added] (See circles 40-43 for full letter).

Minnesota and Wisconsin have set up web sites for their residents that contain information about how to purchase prescription drugs from Canada. Public health officials from both states traveled to Canada to investigate and identify pharmacies that had programs and practices in place that satisfied safety requirements. As a result, they identified recommended Canadian pharmacies for residents seeking to purchase prescription drugs from Canada. The web sites also provide a series of helpful safety tips for residents seeking to purchase prescription drugs from Canada. The FDA contends that these websites violate the FDCA, but has taken no action to stop these states from providing this information to interested parties. Officials from Wisconsin and Minnesota believe that these web sites, which merely provide information so that people can make informed decisions, do not run afoul of the FDCA.

The FDCA is not the only federal statute relevant to this analysis. In 2000, Congress weighed in on the importation debate when it passed the so-called MEDS Act of 2000. This bill, which was signed by President Clinton, allowed American consumers, pharmacists, and wholesalers to purchase FDA-approved prescription drugs on the international market, including Canada. The bill directed FDA to implement the law, but FDA has declined to do so, claiming that it cannot assure the safety of the products being shipped into the United States. Thus, the MEDS Act, which reflected an effort to clarify the status of drug importation, was never implemented.

In a 2003 hearing in the United States House of Representatives on a proposal to allow for drug importation from Canada, Congressman Dan Burton, Chair of the Committee, made the following statement in response to claims by FDA Associate Commissioner William Hubbard that virtually all drugs imported to the United States from Canada by or for individual U.S. consumers violate the FDCA.

> I, for one, am puzzled [by this claim]. How can the FDA officials feel that Americans are violating U.S. law when three years ago the President [Clinton] signed into law a bill [the MEDS Act] that Congress had passed? This bill clarified that it was legal for Americans to purchase prescription drugs internationally.

> We are a country with three branches of government- Judicial, Executive and Legislative. It is not the FDA's job to make the laws. It is their responsibility to implement the laws that Congress passes. And that includes the MEDS Act. So far, FDA has shirked its responsibility in this area.

Congressman Burton raised a host of questions about whether the FDA's position that drug importation from Canada was illegal was accurate.

Charles Milligan, J.D., M.P.H., the former Medicaid Director of New Mexico and Vice President of the Lewin Group, a national health care consulting group in Virginia, provided technical assistance to the working group. As noted earlier, Mr. Milligan outlined a series of steps that the County could take to ensure a safe and effective program. In addition, Mr. Milligan, a former practicing health law attorney, noted that in his view, the legal landscape is "muddy." Milligan outlined a series of legal arguments that could be made to support the claim that importation of drugs from Canada is legal. He concludes by observing that "the legal issues are unresolved, and are certainly not as clear cut as the FDA would suggest." His letter appears at circle 31-34.

Another factor that muddies the legal waters further is the potential application of the North American Free Trade Agreement (NAFTA). A number of questions have arisen as to whether an importation ban would violate specific provisions of NAFTA. Serious questions have been raised as to whether the FDA's position opposing importation is based on scientific principles or an appropriate risk assessment.[1] If the FDA's actions are deemed arbitrary and capricious, these actions may constitute a disguised restriction on trade within the meaning of Article 712 of NAFTA.

In addition, if less trade-restrictive means exist for addressing any legitimate health or safety concerns (such as a program contemplated in the importation bill that passed the House of Representatives in 2003, or the program outlined in the MEDS Act of 2000, which was signed into law by President Clinton but never enforced by the FDA), an outright ban on importation may also constitute an unnecessary obstacle to trade under NAFTA Articles 712 and 904.

Finally, Article 301 of NAFTA requires that the United States grant "national treatment" to the goods of Canada. This provision is meant to capture the special relationship between the two countries, and the mutual confidence that the two countries have in each other's products. There is a private right of action for violations of NAFTA, although it does not appear that the County would have this private right of action. Instead, the Canadian company that was prevented from doing business in the United States would have standing to file a NAFTA claim against the United States. The NAFTA

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[1] As noted earlier, 8 million prescriptions were filled in Canada in 2003 by Americans, amounting to roughly $1 billion in business. Americans have been purchasing prescription drugs from Canada for years, with no apparent ill effects. As a result, many stakeholders, including but not limited to members of Congress, are questioning whether the ban is a result of scientific analysis, or is arbitrary and capricious.

claims are by no means clear cut. It is conceivable that these provisions of NAFTA would not apply. An international tribunal would make this judgment.

Overall, the existence of NAFTA adds another layer of legal complexity to the overall analysis.

B. Tort Liability Implications for the County

Potential tort liability is an additional legal issue that must be considered in making the determination as to whether to implement a voluntary program of drug importation for current and retired employees. In an August 25, 2003 letter to the Deputy Attorney General of California, the FDA remarked that the state of California could be potentially liable in tort if a California citizen were injured by a drug that the state purchased in violation of federal law, but noted it had not researched, nor did it have any advice, on the issue. Moreover, the opinion did not discuss the issue of whether a municipality may be immune from suit under principles of sovereign immunity. A former Department of Justice attorney, writing in a recent issue of the Legal Times (March 1, 2004), opined that municipalities who put drug importation programs in place confront potential tort liability. No filings or case law were cited to show that such theories would ultimately be successful.

As noted above, there were 8 million prescriptions filled in Canada for Americans last year for a total of roughly $1 billion in business. While the Committee continues to search, we are unaware of any tort cases that have been filed by Americans arising out of the importation of drugs from Canada. At the public forum, Mr. Stan Gordon, representing an organization that runs buses to Canada, reported very high marks from users. Nonetheless, it is still necessary to look at tort liability issues because it only takes one negative incident to trigger a lawsuit.

From a tort liability perspective, it would be important to investigate whether the County would have potential immunity from suit under principles of sovereign immunity. Two additional keys to minimizing exposure are to (1) ensure that significant due diligence is performed before a program is put into place so that safety is certain; and (2) draft a disclaimer that will ensure that the users understand the risks of the program, understand that it is voluntary, and agree to participate.

One may question whether it is possible to draft a disclaimer in this context. There is a Maryland Court of Special Appeals case that speaks to the validity of disclaimers. One question is whether such a waiver would be deemed contrary to public policy. In *Seigneur v. National Fitness Institute, Inc.,* 132 Md. App. 271 (Md. App. 2000), the Maryland Court of Special Appeals affirmed a health club's summary judgment motion finding that an exculpatory clause signed by a former member expressed a clear intent to release the health club from all acts of negligence. The Court rejected plaintiff's argument that the health club provided an essential public service such that the exculpatory clause would be "patently offensive" to citizens of Maryland.

In its opinion, the court identified exceptions where the public interest will render an exculpatory clause unenforceable, specifically where i) the bargaining power of one party to the contract is so grossly unequal so as to put that party at the mercy of the other's negligence; and ii) when the transaction involves the public interest. The court explained that one party has decisive bargaining power over the other party when the service offered is "of great importance to the public", "essential in nature", and is considered "a practical necessity for some members of the public." *See id.* at 283-84.

Facilitating the purchase of prescription drugs could be considered all of these things. However, the court stated that the ultimate determination of what constitutes the public interest must be made considering the "totality of the circumstances of any given case against the backdrop of current societal expectations." *Id.* at 287. The court went on to identify transactions affecting public interest as those involving the performance of a public service obligation, including transactions "that are so important to the public good that an exculpatory clause would be 'patently offensive,' such that 'the common sense of the entire community...would pronounce it invalid." *Id.* at 287.

In this instance, factors that would support the validity of such a disclaimer include the uniformly positive experiences of millions of Americans who import drugs from Canada, the careful thought that would go into a County program, and the fact that it is voluntary. No person has to participate. Anyone who wants to continue purchasing prescription drugs from the United States will be able to do so.

As noted above, Wisconsin and Minnesota have established web sites to assist people who want to purchase prescription drugs from Canada. These web sites contain lengthy notices and disclaimers that may be useful if the County chooses to go forward with a program. It may be useful to touch base with other municipalities that have programs in place to determine whether what disclaimers they are using.

Overall, from a tort liability perspective, if a program were to be implemented, it would be important to craft a careful disclaimer, and to perform the necessary due diligence so that the program is unquestionably safe.

C. Overall Legal Picture

While the legal landscape is muddled, both domestically and under NAFTA, a few things are clear. Nobody who purchases drugs from Canada for personal use has ever been sued by the FDA. Their practice has been not to take action against individuals who import drugs for personal use. Thus, people who choose to participate in this program will not be sued by the FDA.

In addition, although Springfield, Massachusetts, and Montgomery, Alabama have had programs in place for months, the FDA has not sued them, and has not sued any other municipality or government entity that has a program in place. In fact, the Boston Globe has reported that Associate Commissioner William Hubbard told a state legislative panel in Massachusetts that the FDA does not intend to take action against Springfield. In this same article, Commissioner Hubbard was quoted as stating that enforcement would be

directed towards "businesses that sell commercial quantities of drugs" from overseas and that the FDA was "not considering legal action against cities or states." [*FDA Eases Stance on Importing Medicines,* Boston Globe, 10/24/2003 Circle 44]. At the recent public forum, Commissioner Hubbard, when asked about this article, indicated that this was not precisely what he said. However, the article appeared in October 2003, after the Springfield program had been in place for months. As of today, no lawsuit has been filed against Springfield or any other municipality. As Commissioner Hubbard noted at the forum, "There is a question as to whether FDA would take action against any given individual or entity." He later clarified further the FDA's position: "We certainly would sue another public official with great reluctance...The good guys shouldn't be fighting the good guys."

In the importation context, the cases that the FDA has litigated have all been against American based intermediaries who were middle people in drug importation programs. In those cases, the FDA filed an action under the FDCA seeking an injunction for the company to cease and desist its actions. If a lawsuit were filed against Montgomery County, it is fairly clear that it would closely resemble the lawsuits filed against the intermediaries. Commissioner Hubbard essentially acknowledged this in the recent forum. Thus, as a practical matter, the most plausible "worst case" scenario for the County, in fact, the only plausible scenario is a federal lawsuit seeking an injunction directing the County to terminate the program.

The Bush Administration is a strong supporter of free trade generally, and the North American Free Trade Agreement in particular. The inconsistency between Administration support for NAFTA on the one hand, and efforts to restrict importation of drugs from Canada, may explain in part the federal government's reluctance to sue municipalities and to take action against Canadian companies such as CanaRx that are working with American municipalities.

Tort liability is a possibility under the County's current program, and would certainly be a possibility under a program of drug importation.

7. Cost Issues

The Committee considered at length what savings can be achieved from a drug importation program. The unions and agencies have worked very hard to implement a host of creative solutions to contain health care costs, including but not limited to studying the feasibility of drug importation. Some of these are listed in circles 45-49.

Two caveats are in order at the outset. First, savings estimates made by other jurisdictions have sometimes assumed that all eligible employees would participate. Since participation would be voluntary, and since employees would have many questions at the outset and perhaps thereafter, assumptions about participation rates must be realistic. One real world indicator is the experience of Springfield, Massachusetts, which reported a 31% participation rate in December 2003.

Second, at some point prices will be affected by the law of supply and demand, particularly if large employers, as opposed to individuals alone, become important players in drug importation. Some drug companies, for their part, have already started to restrict exports to Canada, although questions have been raised as to whether these drug companies are violating antitrust laws.

That said, savings can still be considerable. For example, the graphs on circles 17 and 18 prepared by Wes Girling suggest that under a full participation scenario, MCPS could save $400,000 on Lipitor purchases and $500,000 on Prevacid purchases alone.

Another cost analysis appears in the testimony delivered by MCEA President Bonnie Cullison at the Committee's February 23 public forum. (See circles 50-56.) The analysis estimates savings for all agencies combined at $14.9 million if all eligible employees participate. The analysis also estimates that more realistic participation rates of 25% and 40% would still produce savings of between $3.7 and $6.0 million.

8. Other Ways to Maintain Benefits and Control Costs

As this Committee pursued issues related to drug importation, we discussed other important initiatives that we commend to the Management and Fiscal Policy Committee and the full Council for further review. These initiatives can help to control costs, and controlling costs – as several of our union participants in particular pointed out – is essential to maintaining benefits rather than reducing them, as so many employers elsewhere have done.

One initiative, as recommended last year by the Holloway Task Force and the MFP Committee, is to accelerate joint procurements of health insurance. All of the new strategies examined by the Holloway Task Force can be found at circle 57. The agencies' limited joint procurements to date have worked well, and with a still larger pool there can be additional economies of scale. We noted that agencies now pay often different prices for prescription drugs. It is wasteful that the cost to the County of Lipitor depends on which agency is purchasing the drug. All agencies should be able to achieve the lowest possible prices.

Other initiatives we discussed are summarized well in MCEA President Bonnie Cullison's testimony. Agencies should:

- Encourage the use of generic over brand name drugs when available. For example, while a 30-day supply of 20 mg of Prozac costs $165, its generic equivalent, Fluoxetine, costs just $63, or 62% less.

- Encourage mail-order purchases of maintenance drugs. For example, a 90-day supply of 10 mg of Lipitor costs $230 retail but just $165 mail-order, or 28% less.

Agencies now differ widely in their employees' use of mail-order. M-NCPPC has sharply increased use of mail-order by providing a strong financial incentive illustrated in

the table on circle 58. MCPS now requires retirees to use mail order for maintenance drugs. Real cost savings can be achieved through expanded use of mail order.

- Incorporate drug formularies into prescription plans to promote effective treatments at the most affordable price.

- Purchase expensive biotech drugs directly from the manufacturer via specialty pharmacies.

- Expand the use of prescription discount cards. For example, the Office of Human Resources has just announced that effective April 1, 2004 County Government indemnity plan participants can use a Caremark discount card to purchase drugs at over 55,000 participating pharmacies nationwide. Discounts are about 15% for prescription drugs and as much as 50% for generic drugs.

9. Strategies for Reducing Drug Costs for County Residents At Large

During the course of the Committee's review, we frequently received inquiries from County residents as to whether they could participate in the County's drug importation program, if one were put in place. Although the plan under study is limited to County employees and retirees, we did identify at least one program that may be beneficial to residents without prescription drug benefits, and cost the County nothing. It may be possible to set up a prescription drug discount card program for residents. It would have savings similar to those mentioned above—a 15% discount for prescription drugs and up to a 50% discount for generic drugs. This simply involves the County leveraging its purchasing power to benefit not only employees, but any resident of the County.

Many residents already have health plans that cover prescription drugs, and therefore would not benefit from participation. However, many residents, especially the more vulnerable who have no or minimal health coverage, are paying full retail price for their prescriptions. This program would enable them to get a discount on their drugs. There is no substitute for meaningful reform at the federal level. However, until such reform occurs, this program may help many people in need and merits further review.

Residents are also able to use the Minnesota or Wisconsin websites that have been operating for a number of months without any detrimental outcome.

http://www.state.mn.us/cgi-bin/portal/mn/jsp/home.do?agency=Rx
http://www.drugsavings.wi.gov/

10. Findings and Recommendations

The Committee concludes that a voluntary program that allows employees, retirees, and their dependents to order maintenance drugs from an approved Canadian supplier makes sense.

A. Is It Safe?

The Committee concludes that a program can be developed that would ensure the safety of participants. It would require considerable due diligence and input from public health professionals, but it has been done elsewhere in the US and can be done here.

The program should include only maintenance drugs. It should not include biomeds. A group of benefits managers, public health officials, and consultants should take up the task of devising a program that takes into consideration the following elements:

- Only FDA-approved medications;
- Maximum 90-day supply of any given medication (to discourage re-sale, and allow for regular monitoring);
- Prohibit importation for the "first fill" of any given medication (to establish it is effective and tolerated by the patient);
- Permit importation only of County-designated maintenance medications for chronic conditions;
- The prescription must be written by the employee's local treating physician;
- The County should carefully select the approved Canadian vendor(s) according to criteria such as on-site physicians, 24 hour call center staff, and a record of compliance with all Canadian licensure laws;
- The Canadian vendor(s) must register with the Secretary of the federal Department of Health and Human Services ("HHS");
- The prescription must be for personal use by the County plan participant, and not for resale; and
- The prescription must be in the form of a final finished dosage that was manufactured in an establishment registered with the FDA.

B. Is It Legal?

The Committee concludes that while there is some risk of litigation due to the muddled legal picture, the risk of actual litigation is low. The FDA has not taken action against any municipality, and it appears clear that the most likely action, if any, would be a civil suit for injunctive relief (e.g., cease and desist). There are a host of potentially viable defenses that can be raised in the unlikely event of litigation by the federal government. There should be further discussion with the County Attorney about the civil and criminal provisions of the Food, Drug and Cosmetics Act, as well as potential tort liability.

C. Is It Cost-Effective?

The Committee concludes that Montgomery County could save millions of dollars in prescription drug costs by implementing a voluntary Canadian drug importation program for employees and retirees. These savings could reach as high as $6 million per year with 40 percent participation. Participation in the voluntary program is the primary variable that affects the amount of money saved. If most or all employees participated, the savings could reach $15 million per year. If there is a way to capture

savings for employees that currently use health plans that embed prescription costs, the savings would increase.

D. Are There Other Important Strategies?

The Committee concludes that there are considerable potential savings in restructuring the current disparate prescription benefits programs into a single program that takes advantage of economies of scale. There are also important cost-saving strategies involving generic drugs and mail order for maintenance drugs. The MFP Committee and the County benefits managers should pursue all of these strategies assiduously. However, the programs should be subject to negotiation, and no program should be put in place unless it has been the subject of collective bargaining.

The Committee concludes that the potential inclusion of County residents in drug discount programs should be examined. The health and economic benefits for residents without insurance or drug benefits could be considerable.

E. Recommendations

The Committee recommends that Montgomery County:

1. Design a health benefits program for employees and retirees that includes the option of safely ordering FDA approved prescription drugs from Canada at significantly reduced cost. The program should be limited to certain maintenance drugs, and should exclude bio-medications. The program should increase incentives for the use of any domestic or Canadian mail order option.
2. Restructure existing health benefits to take advantage of economies of scale that can reduce overall costs to the County and employees and retirees.
3. Investigate fully the potential for establishing a prescription drug benefits program for County residents.

11. Next Steps

The Committee believes that the following steps should be taken as soon as possible to implement the recommendations.

1. A working group should be convened, composed of representatives of interested unions, benefits managers, public health officials, and other experts as needed, to begin the due diligence necessary to put a voluntary drug importation program in place.
2. Requests for Interest or Proposal for prescription benefits programs with a Canadian mail order option should be issued as part of the current contract cycle to get final estimates on costs and program elements.
3. Consultation with the County Attorney on the provisions of the Food, Drug and Cosmetics Act, and other legal issues should be initiated.

4. Requests for Interest or Proposal for a prescription drug discount benefit that could be made available to County residents should be issued.

Resolution No.: 15-384
Introduced: November 4, 2003
Adopted: November 4, 2003

COUNTY COUNCIL
FOR MONTGOMERY COUNTY, MARYLAND

By: Councilmembers Perez and Leventhal

SUBJECT: Securing Lower-Price Prescription Drugs for Current and Retired Employees of County Agencies

Background

1. The nation's health care system suffers from chronic problems of sharply rising costs and inadequate coverage. The soaring price of prescription drugs has had an especially serious impact on the millions of Americans who need them, but have been unable to afford them.

2. State and local governments have undertaken numerous health insurance cost containment activities, including altering benefit packages, cost sharing arrangements, and contracting mechanisms, all in an effort to continue affordable health insurance for state and local governmental employees. Consistent with this national trend, Montgomery County has undertaken these efforts. In recent years, the unions representing various Montgomery County and school system employees have worked closely and collaboratively with their respective agencies to implement cost containment measures that have saved the county and its employees millions of dollars in health insurance premiums.

3. Notwithstanding these cost containment efforts, the cost of health insurance generally, and prescription drugs in particular, continue to soar. In the absence of a national solution to the prescription drug problem, an estimated two million Americans and a growing number of non-profit groups purchase drugs in Canada and Europe, with savings often over 60 percent. Busloads of senior citizens travel regularly from communities in New England to Canada to purchase prescription drugs, while other United States residents have purchased lower cost prescription drugs on-line.

4. The rising cost of prescription drugs continues to pose a substantial problem for state and local governments who are attempting to identify additional innovative insurance cost containment practices that do not adversely affect their employees' health benefit plans. As a result, a number of state and local governments have begun to seek lower-cost prescription drugs from Canada for their employees. The City of Springfield, Massachusetts has already started its program, which it believes could save $4 million of its current annual $9 million cost for prescription drugs if all 9,000 of its active and retired employees choose to sign up, as 1,000 already have. Among the states considering a similar approach are Illinois, which spends $340 million on prescription

drugs for 230,000 active and retired employees, and estimates that buying prescription drugs from Canada could save $91 million per year. Iowa, which spends $54 million for 70,000 employees, is also looking into purchasing prescription drugs from Canada. The Governor of Minnesota is considering a similar program to import prescription drugs from Canada that would include as one feature the elimination of drug co-payments for state employees who shop at an authorized Canadian pharmacy.

5. The Food and Drug Administration contends that the safety of these imported drugs cannot be assured and that some have been found to be counterfeit, mislabeled, or expired. Many experts dispute the claims of the FDA, and on September 22, 2003, the U.S. House of Representatives, by a vote of 243-186, approved legislation directing the Department of Health and Human Services to establish a system for importation of FDA-approved drugs from FDA-approved facilities in Canada, the European Union, and seven other nations. A bipartisan group of Senators has introduced a similar bill in the Senate.

6. The tax-supported agencies of Montgomery County – County Government, Montgomery County Public Schools, Montgomery College, and the Maryland-National Capital Park and Planning Commission – are spending a total of more than $60 million this year for prescription drugs for about 38,000 active and retired employees and their families.

7. Current and retired employees of these agencies could benefit immensely from being able to purchase prescription drugs from Canada. Depending on the level of participation, the County could realize tens of millions of dollars in potential savings per year. In addition, current and retired county employees could also realize substantial reductions in their prescription drug expenses.

Action

The County Council for Montgomery County, Maryland approves the following resolution:

The Council requests the Holloway Task Force to continue to examine the issue of securing lower priced prescription drugs for current and retired employees of County agencies and urges them to bring the conclusions to the Council and the Management and Fiscal Policy Committee as soon as possible, encouraging the input of County Government, Montgomery County Public Schools, Montgomery College, the Maryland-National Capital Park and Planning Commission, and the Washington Suburban Sanitary Commission, and attempt (1) to estimate how many County-insured employees, retirees and dependents would voluntarily participate in a Canadian drug purchasing program if such participation resulted in lower out-of-pocket costs for the employee or dependent, and (2) to estimate how much money might be saved for the County in its insurance purchasing as a result of the estimate derived in (1).

This is a correct copy of Council action.

Mary A. Edgar

Mary A. Edgar, CMC
Clerk of the Council

Excerpts from the Report of the Montgomery County Task Force on Health Benefit Improvements

November 25, 2003

County Council Resolution 15-384, Securing Lower-Priced Prescription Drugs for Current and Retired Employees of County Agencies

On November 4, 2003, the County Council adopted a Resolution directing this Task Force to examine the issue of securing lower priced prescription drugs for current and retired employees of County agencies and to report their conclusions to the Management and Fiscal Policy Committee. The Task Force's original charge was ***"to review employee health plans across County agencies with an objective of proposing realistic, but cost bearable, ways of improving benefits and strengthening coverage",*** and the Task Force has completed that original charge.

One of the options identified earlier in this report as a tool that could be employed in efforts to control rising health care costs was the strategic use of both agency and interagency joint labor/management committees. The Task Force feels that the charge contained in Council Resolution 15-384 presents an opportunity for such an interagency committee to determine the potential cost savings associated with purchasing prescription drugs from Canada, as well as to identify the critical issues such as safety, legality and liability involved with pursuing this type of alternative. It also creates an efficient hand-off of responsibilities in this area to a more permanent body with the ability to examine a host of other such potentials designed to control the County's health care costs.

An interagency joint labor/management committee would be able to leverage information from various sources, including other entities that have implemented or are considering similar options, and the consultants under contract with the respective agencies for group insurance issues. The Task Force recommends the immediate establishment of such an interagency joint labor/management committee.

As an initial work plan, the Task Force recommends the following methodology;

- Identify potential cost savings associated with a Canadian drug purchase initiative. The committee would determine a common basis for estimating potential cost savings across the agencies. Each agency would use the same criteria for identifying the types of drugs to consider in a savings estimate, e.g., maintenance medications currently purchased under mail order.

- Once determined, the current costs from each agency would be re-priced using known discount factors associated with Canadian prices versus comparable U.S. prices.

- The percentage of total potential savings from a *voluntary* program could be deduced through the application of a range of participation rate assumptions. These rate assumptions would be based on a combination of information gathered from other entities and threshold out-of-pocket costs per member per month applied to the data gathered from the agency carriers.

- The interagency committee should contact and solicit detailed information from the numerous other state and local jurisdictions that are also studying or implementing re-importation of prescription drugs from Canada. Specifically, the committee would gather information related to such issues as:
    - legality
    - safety
    - liability
    - supply (adequacy and source)
    - program administration, and
    - plan design

- The interagency committee should solicit written input from the various benefits consultants that work with the agencies and their unions on their advice, recommendations, and suggestions for a jurisdiction considering a re-importation program.

Potential cost savings and an analysis of the surrounding issues associated with Canadian drug purchase will hopefully provide an effective and measured roadmap to next steps in this area.

Montgomery County Agencies Questionnaire on Prescription Drugs

A working group convened by the County Council, consisting of labor and management representatives from the Montgomery County agencies, is looking at methods of preserving the integrity of agency benefits through effective cost management. As part of this task, the group is reviewing alternatives associated with the purchase and delivery of prescription drug benefits to employees and retirees of County agencies. Please take a few minutes to complete the questionnaire below. Your responses will be anonymous. Thank you!

---

1) Which agency do you (or did you) work for?

- Montgomery County Public Schools
- Montgomery County Government
- Montgomery College
- MNCPPC
- WSSC
- Housing Opportunities Commission
- Other (please specify)

If you selected other please specify:

2) Are you:

- Active
- Retired Medicare eligible
- Retired not Medicare eligible

3) Do you have prescription coverage through your agency?

- Yes
- No

4) Are you on maintenance medications? *Maintenance medications are medications that you take regularly over the long term such as heart medications and cholesterol medications versus short term medications such as antibiotics*

- Yes
- No

5) Are you aware that your prescription benefit program offers a mail order option for maintenance medications? *Mail order provides a cost effective way for you to order up to a 90 day supply of maintenance medications for delivery directly to your home*

- Yes
- No

6) Do you currently use the mail order?

Yes
No

7) Would you use mail order if you could save money?

Yes
No
No. I am not on maintenance medications.

8) Are you concerned about the increases in the costs of drugs?

Yes
No, because I can afford the increases
No, because I have a flat co-pay, so the increases do not affect me
No, because of other reasons

9) How many maintenance medications are you currently using?

1-2
3-4
5-6
more than 6

10) How long have you been using mail order?

less than 6 months
6 months to a year
1 to 2 years
2 to 3 years
More than 3 years

11) If you do not use mail order, why not (check all that apply)?

- ☐ Safety concerns
- ☐ Not as convenient as going to my local pharmacy
- ☐ Want access to my pharmacist
- ☐ No cost savings to me versus going to my local pharmacy
- ☐ Did not know that the mail order program was available
- ☐ I am not on maintenance medications
- ☐ Other (please specify)

If you selected other please specify:

12) If you had the option of voluntarily using a mail order program that purchases drugs from an approved pharmacy

(6)

in Canada for your maintenance medications and would help save your agency money on prescription costs and help preserve your current level of benefits, would you?

Yes
No
No. I am not on maintenance medications.

13) If *No*, why not (check all that apply)?

- [ ] The same reasons why I do not use the current mail order option
- [ ] Additional safety concerns about drugs from Canada
- [ ] Legal concerns, e.g., I don't want to participate in a program, which may not be legal
- [ ] Other (please specify)

If you selected other please specify:

14) If you answered *No* to question 12, what would make you reconsider using a mail order program which purchased drugs from Canada for your maintenance medications (check all that apply)?

- [ ] A significant cost savings to me
- [ ] Prescriptions delivered in original manufacturer's packaging
- [ ] Knowing that many other Americans were buying drugs safely from Canada with no bad experiences
- [ ] Knowing that the Canadian mail order pharmacy had been selected because it has been inspected by the County and complies with a set of safety standards
- [ ] Other (please specify)

If you selected other please specify:

15) Do you think the County agencies should provide an option of using a mail order program, which purchases drugs from Canada, even if the program is strictly voluntary?

Yes
No
I would need more information

16) Do you usually check to see if you can receive the generic version of a drug (check all that apply)?

- [ ] Yes, because the cost is so much lower for the generic version of the drug
- [ ] Yes, because the generic version has the same active ingredients as the brand name drug
- [ ] Yes, because my doctor recommends the generic version of the drug
- [ ] Yes, because my medical or drug plan recommends the generic version of the drug
- [ ] No, I believe that the brand is better than the generic version of the drug
- [ ] No, since I don't have to pay much more for the brand over the generic, I prefer to have the brand

7

☐ No, I just don't bother

Thank you very much for answering this questionnaire!

Submit Survey

This survey was created with WebSurveyor

Montgomery County Council

Forum on Purchase of Prescription Drugs from Canada

February 23, 2004

(9)

Overview

- The residents of Montgomery County help support the budgets of five County agencies – the Montgomery County Government (Government), Montgomery County Public Schools (MCPS), Montgomery College (MC), the Maryland National Capital Park and Planning Commission (MNCPPC) and the Washington Suburban Sanitary Commission (WSSC)

- Benefits are provided to over 40,000 active and retired employees and their qualified dependents

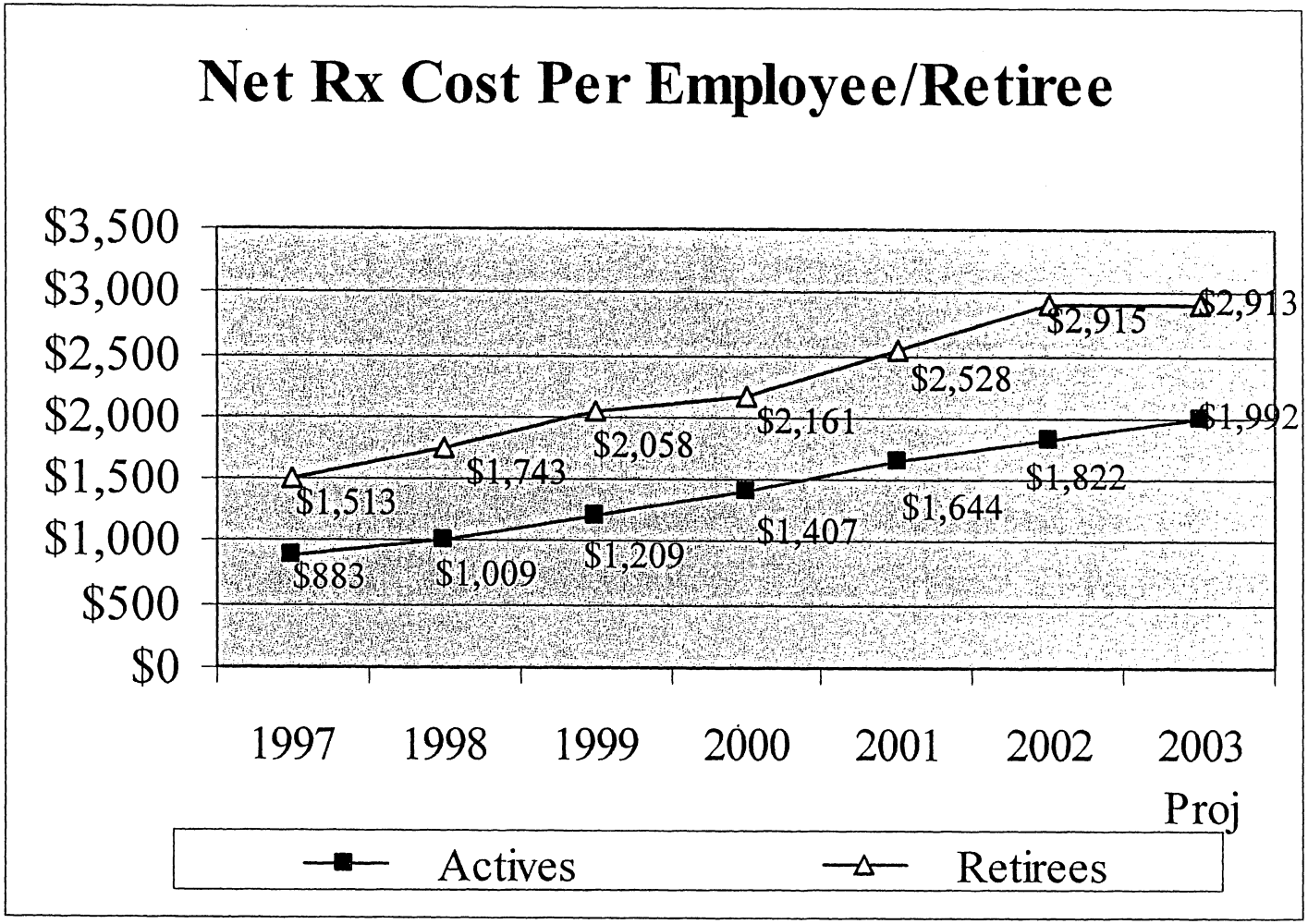
- Agencies spent in excess of $330,000,000 on health coverage in 2003

- Estimated $70 million of that on prescription drugs

Agency Experience

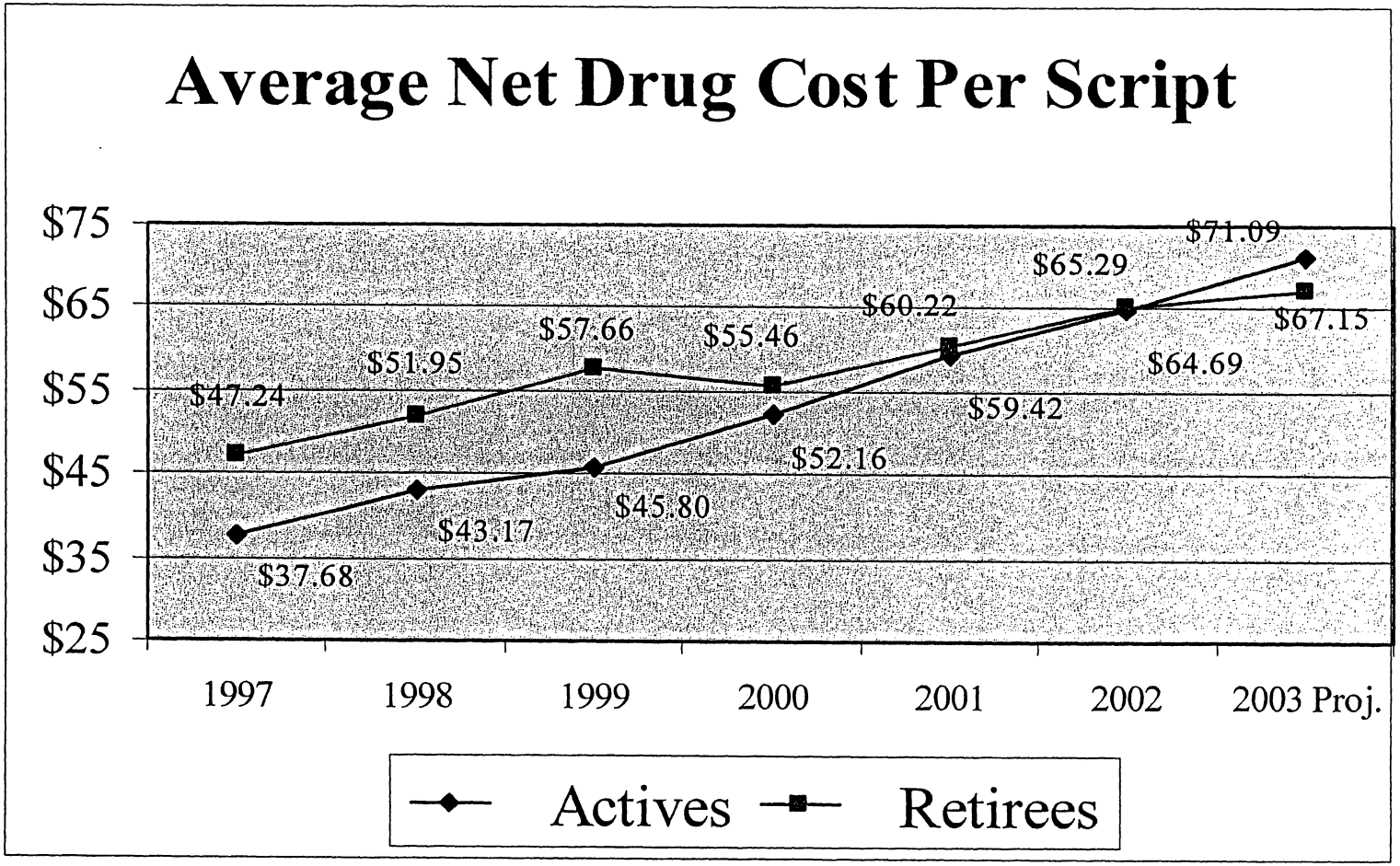
- Data on the cost of prescription drugs is sometimes difficult to extract from health plans
- MCPS and MNCPPC provide stand-alone programs where the cost is more readily captured
- MCPS experience is representative of the experience of other county agencies

Trend Data

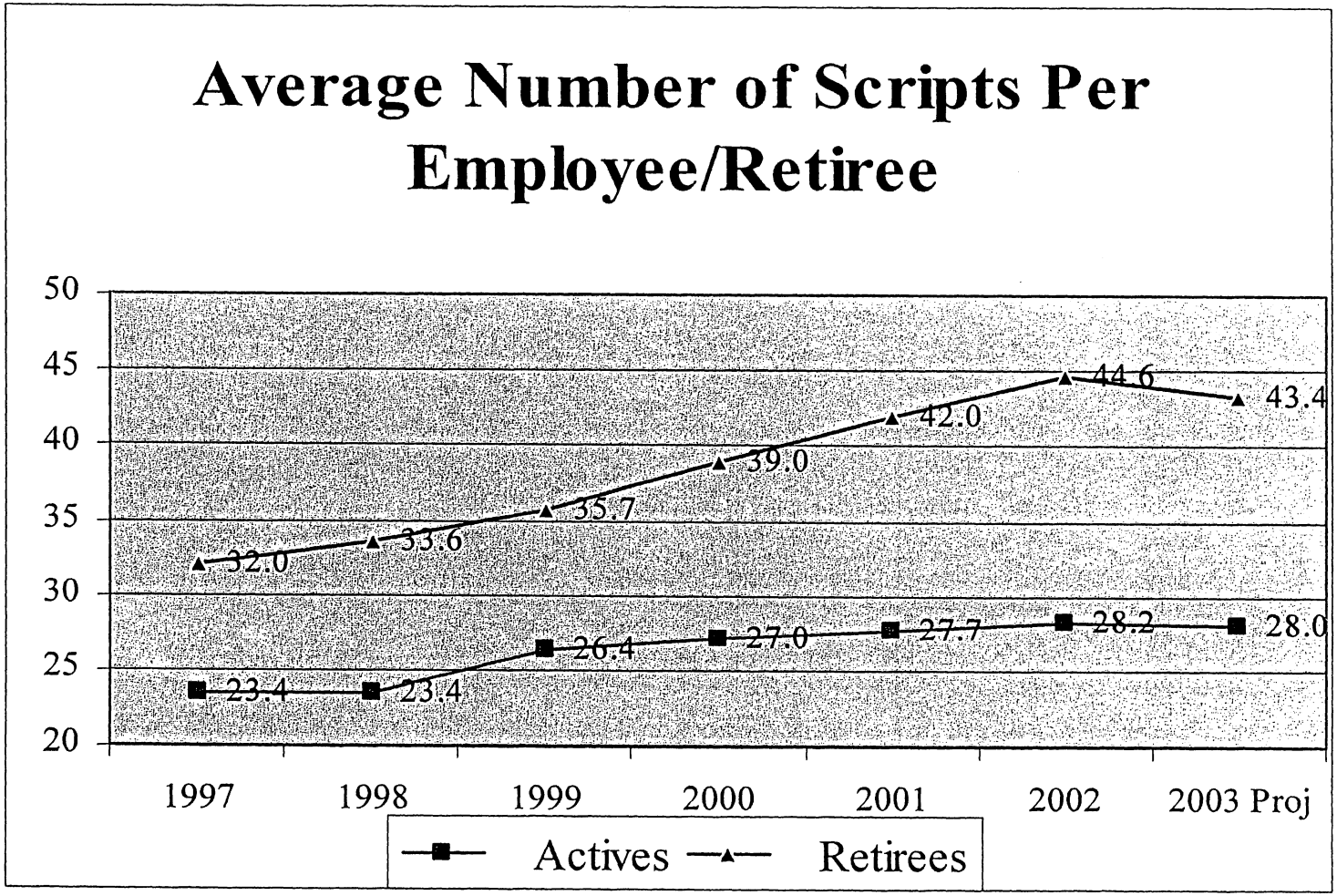


(12)

Trend Data


Average Net Drug Cost Per Script
$75
$65
$55
$45
$35
$25
$47.24
$51.95
$57.66
$55.46
$60.22
$65.29
$71.09
$37.68
$43.17
$45.80
$52.16
$59.42
$64.69
$67.15
1997
1998
1999
2000
2001
2002
2003 Proj.
Actives
Retirees

Trend Data



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Utilization

- Agencies Taking Steps to Control Utilization
  - *Use of Generic Drugs*
  - *Three tier formulary plans*
  - *Mail-order for maintenance drugs*
  - *Step therapy protocols*
  - *Specialty pharmacies for Bio-tech drugs*

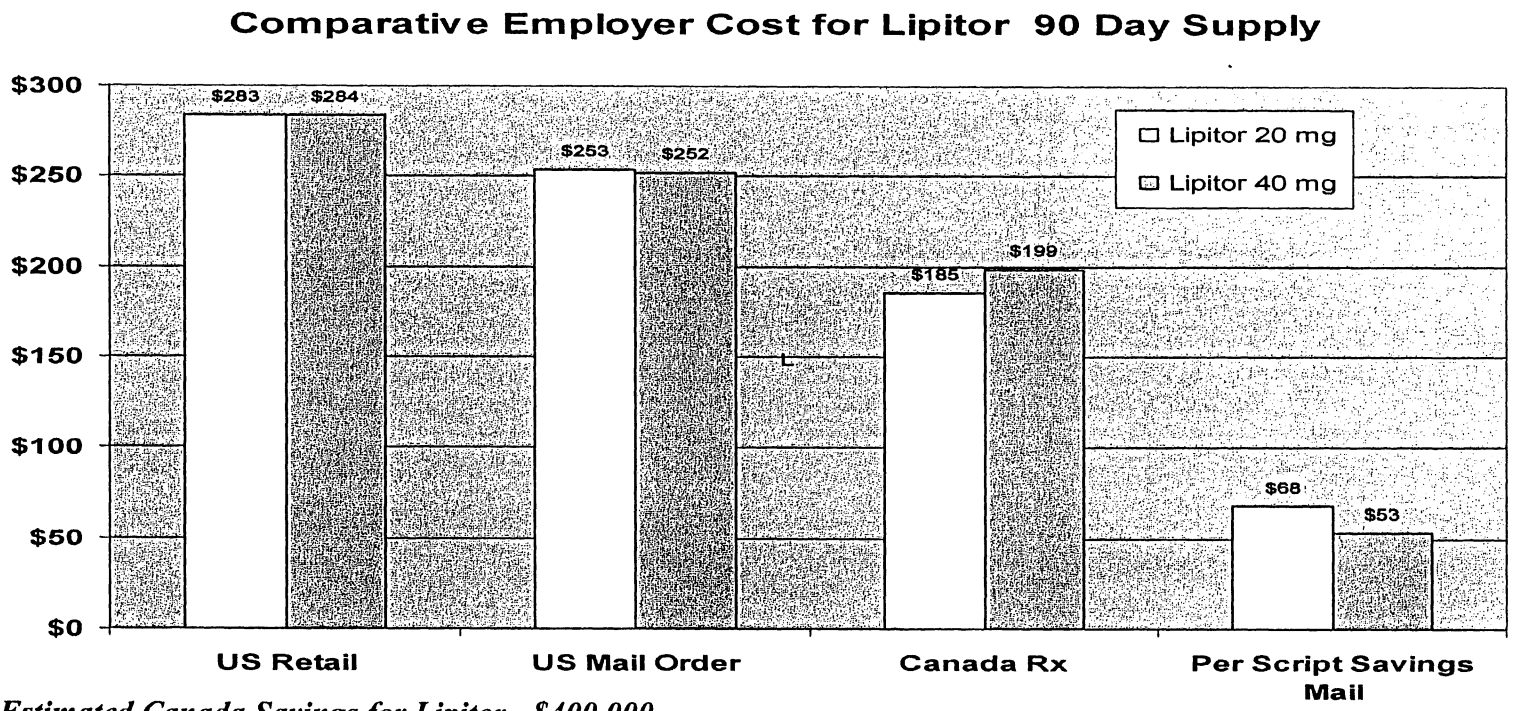
Why Canada?

- The cost of drugs in Canada is regulated by the Government
- Same drugs cost less in Canada
- MCPS could have saved $4.0 million

Some Examples

Lipitor

- In 2003, MCPS plan participants filled 10,695 scripts for lipitor at retail pharmacies and 8,127 through the mail order program.
- 2003 Cost – $2,700,000



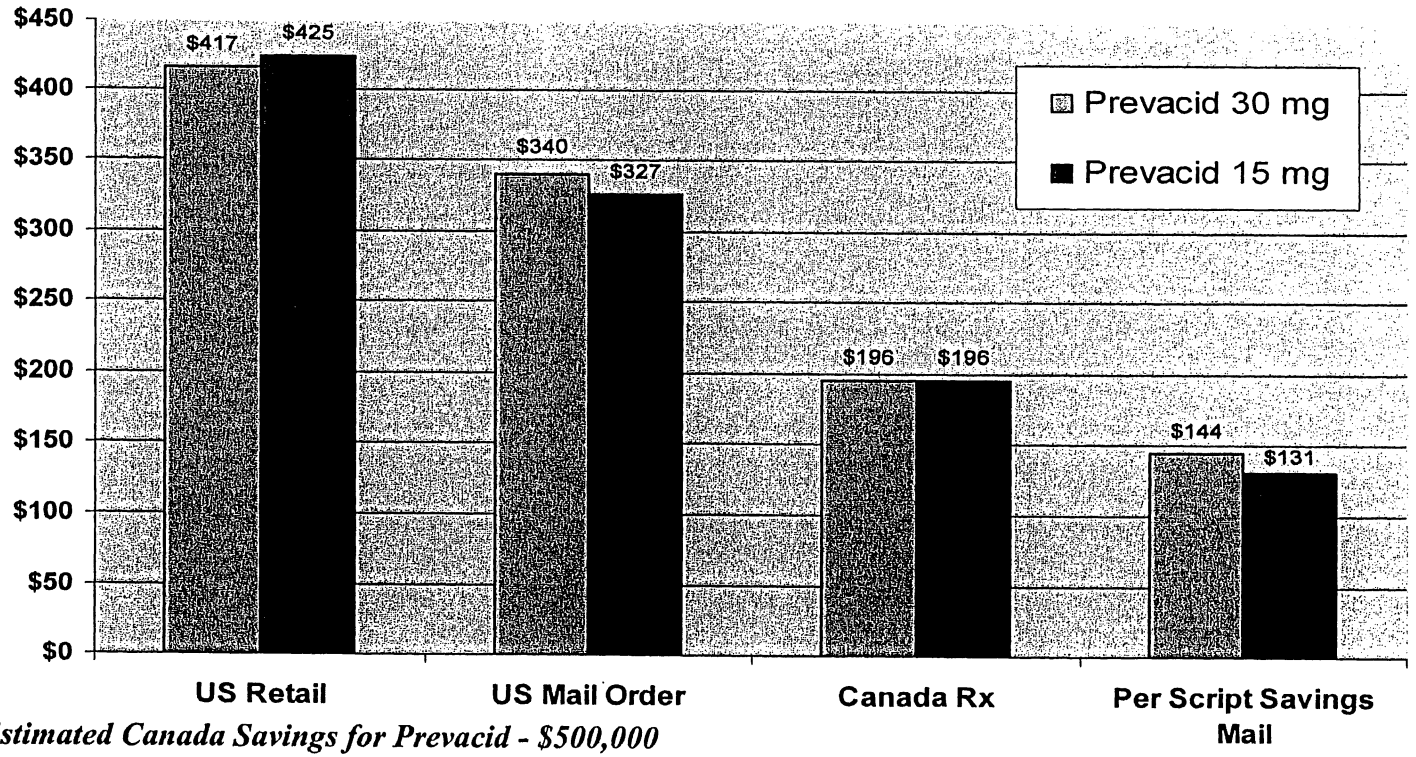
Estimated Canada Savings for Lipitor - $400,000

Some Examples (continued)

Prevacid

- In 2003, MCPS plan participants filled 5,023 scripts at retail pharmacies and 2,771 through mail order.
- 2003 Cost – $1,600,000

Comparative Employer Costs for Prevacid 90 Day Supply



Estimated Canada Savings for Prevacid - $500,000

Needed for Success

- Success depends on many variables, including:
  - How the plan is designed
  - Incentives for plan participants to purchase through Canada
  - Overcoming legal hurdles

Springfield, MA
December Results:

- Eligible Employee's – 10,031
- Enrolled Employee's – 3,112 31%

Issued Prescriptions	2,434
Local Pharmacy Cost	$598,691
CanaRx Billing	$355,086
Savings	$243,605
	40.70%

I Made a Drug Deal, and My City Thanks Me

Michael Albano
August 10, 2003; Page B3

SPRINGFIELD, Mass.

Last March, I did something a lot of Americans are doing these days -- I went to Canada to buy some inexpensive prescription drugs.

You see, my 13-year-old son, Mikie, is diabetic, and he needs a constant supply of insulin, syringes, lancets and test strips. With his prescription in hand, I went to CanaRx -- a pharmacy in Windsor, Ontario, that turned out to be pretty much indistinguishable from my neighborhood CVS. I visited a few of their outlets and examined the product -- same medications, same manufacturers, same sealed containers as in the United States. I visited CanaRx's central office and interviewed some of the company's physicians and pharmacists and health-care specialists. I talked to people about their mail-order business. A year's worth of diabetes medications that would have cost $768.84 back home cost just $555.60 in Windsor.

So I made a deal. A big deal. Because I'm not just Mikie's father -- I'm the mayor of **Springfield**, Mass., and the larger purpose of my visit was to check out low-cost prescription drugs for the 7,000 city employees and 2,000 retirees whose health care is to some extent my responsibility.

In what we think is the only program of its kind in the United States, **Springfield** last month began signing up participants in a municipal system for buying drugs from a Canadian supplier. This made a certain splash in the national news -- we've been mentioned in several newspapers, and I've been interviewed on radio and TV.

It did not make us many friends in Washington, where Congress is still debating whether to legalize the reimportation of drugs that are produced in the United States but sold for lower prices abroad. Even my friend and fellow Democrat, Sen. Ted Kennedy, told people I made a great presentation on CNN, but he still didn't agree with my ideas. But I'm making a lot of friends around here. Most people in **Springfield** seem to agree it was the right thing to do for my fellow city employees, and for my city.

Springfield is home to 152,000 people, mostly blue-collar, and in the past few years it has taken a double hit from the explosion of health care costs and the implosion of the economy. In 1996, the year I took the oath of office, the city's total health care costs were $33 million. This year the costs will exceed $64 million.

In 1996, prescription medication costs for our employees and retirees were $9 million.

This year they're more than $18 million. Next year, those costs could increase another 20 percent.

Meanwhile, revenues are dropping, state and federal aid is dwindling, and we are strapped for cash. **Massachusetts** is reeling from a budget crisis; under state law, the governor has authority to unilaterally impose any cuts necessary to balance the budget. Not long before I went to Windsor, he eliminated $4 million in previously legislated aid to **Springfield**, plus $3.2 million from our share of state lottery proceeds. We're losing federal funds, too, including community development grants. Between the cuts from Boston and Washington, I was compelled in February to reduce the city's workforce by 323 employees, including 76 police officers and 52 firefighters.

That's a lot of lost jobs. And it means a serious drop in security for our citizens.

I'd been thinking for years about how to save money on health care. It's been no secret that people were going over the border to Canada, making an informal end run around the U.S. pharmaceutical companies. And like just about anyone with a computer, I'd been getting inundated with junk e-mails about cheap prescription drugs -- some of them from outside the United States. At a meeting in January with the editorial board of our local paper, the Republican, I floated the idea of getting our medications from Canada. People were surprised, but I noticed that nobody said I was crazy. Our city insurance director, Chris Collins, began looking into various suppliers and found CanaRx in Windsor.

Meanwhile I called my friend Paul Cellucci, former Republican governor of **Massachusetts** and now ambassador to Canada, and asked him what he thought. His trade people replied there might be some legal issues. We had some informal discussions with the U.S. Food and Drug Administration. The FDA had already made it clear that the agency would not seek to halt or prosecute American individuals who went to Canada to buy drugs. That would cover our situation, because under the **Springfield** plan the citizens all buy the drugs individually. The way it works is, the city urges its employees and retirees to sign up. If they do, we provide them with forms from CanaRx to set up an account. When a worker gets a prescription from his or her doctor, he or she mails it to Canada, and CanaRx mails back the medications, just as any U.S. mail order pharmacy would do. Then CanaRx bills the health insurance carrier -- that is, the city of **Springfield** -- just as any U.S. pharmacy would do.

The big difference is, we expect to save so much money that the city can afford to cover the co-pay. That means that it's not just the city that saves money, it's the individual: At $15 a prescription, those co-pays add up. In my case, I'm saving almost $300 a year. That sounds good to me, and I make $95,000 as mayor. The average worker in **Springfield** earns about $33,000 a year, so I presume it means a lot more to him or her. Probably almost as much as that $400 federal dependent tax cut that a lot of us got in the mail last week.

The drugs we expect our employees to buy in Canada are 20 percent to 80 percent cheaper than they would be in the States -- depending on the specific product. Our budget office estimates that, if all 9,000 people currently covered signed up and bought the drugs they're using now, we could save between $4 million and $9 million a year. Right now, the exchange rate is working in our favor, too, though we know we can't

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count on that to last.

Of course, emergency drugs would still be bought in town; if your child has a 102-degree fever, you don't mail away to Canada for antibiotics. It's the maintenance drugs -- for allergies, high cholesterol or blood pressure, diabetes and so on -- that we'll get from across the border, and that will save both the city and its citizens money, month after month.

Every time somebody asks about our plan, they also quote the FDA, which repeatedly warns that it cannot guarantee the "safety" of products from Canada. Well, as mayor, I cannot guarantee my citizens safety with fewer police and firefighters on hand to protect them.

In any case, I'm no more worried about buying drugs in Canada than I would be buying them in Kansas City, where a pharmacist was jailed last year for diluting his customers' cancer drugs. He was caught and prosecuted, and I'm sure that any case like that, or any other dangerous malfeasance, would be caught and prosecuted in Canada. In a country where the government actually controls the cost of prescription medicines, you could argue that protections are stronger than they are here.

Anyway, we're not doing anything I don't firmly believe to be safe. My son injects insulin into his body three times a day, and I would not sign him up for anything I did not completely trust. After all, I'm not just the mayor of **Springfield**. I'm Mikie's father.

Author's e-mail: jmurphy@springfieldcityhall.com

Michael Albano is still hoping to convince his federal representatives to legalize the reimportation of lower-cost drugs.

Return to Search Results

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Order Drugs From Canada

Click to Order Drugs from Canada

Just across the border, citizens in Canada can walk into their corner drugstore and buy the same safe prescriptions we have here, but at a fraction of the price. But too many citizens of this country are forced to make unbearable choices between food and medicine. If the federal government isn't willing to take on the drug companies and fight for more affordable prices, states like Wisconsin will have to lead the way.

This website gives our citizens the ability to buy certain prescriptions at significantly lower prices directly from Canadian pharmacies that our state has visited and found to be safe, reputable, and reliable. It also provides information about SeniorCare, the new Medicare drug benefit, and other programs that may be an option for you.

The goal is to let consumers make an informed choice among all of the available options - including local pharmacies, lower price generics available domestically, and safe Canadian pharmacies.

Thanks for visiting this website. I hope you find it useful.

-- Governor Jim Doyle

Printed Tuesday, March 30, 2004

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Your Savings Options

Many Americans struggle with the high price of prescription medicine. Some people, especially those on a fixed income, end up choosing between food or their prescription medicine. Prescription costs are eating into their household budgets.

This web site educates Wisconsinites about lower-priced prescription medicine that they can buy from Canadian pharmacies. There are many pharmacy sites on the Internet. Wisconsin's site offers buyers an added level of information about the pharmacies listed on this web site.

Is buying prescription medicine from Canada right for you? Only you can decide. Recognize that you can only buy maintenance medicine through this site, that is, medications that are used for a long time to keep a health condition in check. For example, Lipitor is a maintenance medication that controls high cholesterol. Some people with high cholesterol will take this type of medication for the rest of their lives.

Medicine you can't buy through this site includes: controlled substances, medicine that is not available in Canada, generic medicines approved in the United States that are not available in Canada, and vice versa. If you take generic prescription medicine, you may be already getting the best price right here in Wisconsin. Additionally, you cannot purchase medication from this site if the purchase represents your first use of the medication.

To learn more about various savings options, click on the links below.

Tips for cutting costs
SeniorCare +
BadgerCare +
Recent Medicare Changes
Health Insurance Risk Sharing Plan (HIRSP) +

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Ordering Information

Click Here For Important Information About the Legality of Purchasing Medications from Canada

- Payment methods
- Find your medicine
- First time customer forms
- Participating pharmacies
- Shipping policies and fees
- Steps for ordering
- Tips for cutting costs

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"Minnesotans deserve affordable prescription medicine."
Governor Pawlenty

Tues

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Welcome to Minnesota RxConnect Online

" Americans pay more for prescription medicine than the rest of the world. The price differential puts prescription medicine out of reach for too many people. The current situation is unfair and cannot continue. "

Minnesota Governor Tim Pawlenty
Governor's Office

Minnesotans deserve information and access to affordable prescription medications. This website was created to provide Minnesotans information on issues related to prescription medicine, safety and cost-saving tips, and programs to help low-income Minnesotans pay for prescription medications.

This site also provides Minnesotans with information about accessing lower-cost prescription medicine from Canada.

Click here to learn about what's on this website.

Click here to order your prescription from Canada
Prices updated March 15, 2004

Quick Links

- How to use this sit
- Legal information

Click here!
A – Z
List of medic
Prices updated March

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"Minnesotans deserve affordable prescription medicine." Governor Pawlenty

Tues

Step-by-step order instructions

- Steps for ordering

Find your medicine

- Medicine names may be different
- Can't find your medicine?

Pharmacy forms

- First-time customer forms

Prices and payments

- Payment methods
- Pricing policy

Shipping policies and fees

- Total Care Pharmacy shipping information
- Granville Pharmacy shipping information

Click here! A – Z List of medicines Prices updated March 15, 2004

Order Your Medicine from Canada

Step 1

Find your medicine(s) in the A-to-Z list of available prescription medications.
Review the medicine summary page which shows the cost for each pharmacy.
Choose the pharmacy from which you want to order.

Step 2

Print the order summary for the pharmacy from which you want to order. You must **also send an original written prescription** from your doctor, unless you are ordering a refill.

- **If this is your first order from a particular pharmacy,** you also must print the "First-time Customer Form" for that pharmacy. It includes a Customer Agreement that you must sign and send to the pharmacy before it will complete your order. Click here to preview the "First-time Customer Form."
- **If you are ordering a new medication that you haven't taken before,** click here and read this before placing your order.
- **If you are ordering a refill,** you can order by phone by calling the pharmacy's customer service number. If you prefer, you may also order your refill by mailing or faxing an order form.

Step 3

Mail or fax the order summary form to the pharmacy address or fax number on the form, or click here for the address, fax or phone number.

Important: Printing an order summary **does not** place an order with a pharmacy. Prescriptions cannot be ordered electronically through this website. Orders must be mailed or faxed to the pharmacy.

**If you want to place an order but you're not comfortable using the website,
call Minnesota RxConnect at 1-800-333-2433.
RxConnect specialists are available from 8 a.m. to 4:30 p.m. Monday - Friday
to assist you in accessing the appropriate order form(s).**

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CanaRx Services Inc.

Toll free phone: 1-866-893-MEDS (6337) Toll free fax: 1-866-715-MEDS (6337)
P.O. Box 21086 Tecumseh, Ontario, Canada N8N 4S1

SAFETY PROCEDURES

CanaRx Services Inc. is acutely aware of the concerns being raised by various organizations about the safety of the Canadian Drug Distribution System. In a recent meeting between Diane Gorman, the Assistant Deputy Minister of Health Canada and Mark B. McClellan, the Commissioner of the U.S. Food and Drug Administration, Ms. Gorman stated that "Canada's safety record is second to none internationally" and that "Canada's health care system is a defining characteristic of who we are as a nation".

In keeping with these nationally recognized standards, CanaRx consistently strives to maintain the highest degree of safety throughout its operations. The CanaRx Team is the proud sponsor of the SpringfieldMeds Program and as the host Pharmacy Benefits Manager of the Illinois Delegation to Canada; we demonstrated and documented the following safety procedures:

1. All Patients are required to visit their U.S. based Primary Care Physician at least once a year for a complete physical and reassessment of all medication therapy. The U.S. based Primary Care Physician will typically write prescriptions for a period of three months with three refills for a total of one year's supply of medication.

2. CanaRx will not allow the fulfillment of new or first-time prescriptions (prescriptions that the Patient has not previously filled through his/her local Pharmacy). This ensures that all prescriptions dispensed by CanaRx affiliated Pharmacies are for maintenance medications only. In addition, the SpringfieldMeds Drug Formulary is restricted to maintenance-type medications.

3. All Patients are required to complete an Enrollment Form (or have their U.S. based Primary Care Physician complete the form for them) detailing current and previous medical history and allergies, as well as, all medications they may be taking. Once received by CanaRx, this information, along with the original prescription from the U.S. Physician is sent to a licensed, actively practicing Canadian Physician for review. U.S. prescriptions may be sent to CanaRx by fax directly from the U.S. Doctor's office. CanaRx does not accept faxed prescriptions from any other source. Alternatively, the Patient or U.S. Physician may send the original prescription in the mail to CanaRx.

4. If appropriate, the Canadian Physician will issue a Canadian prescription to be filled by a CanaRx affiliated, licensed Canadian Pharmacy. The Canadian Physician may contact the Patient or the U.S. Primary Care Physician directly to verify information before issuing the Canadian prescription.

5. A licensed, accredited Canadian Pharmacy then fills the Canadian prescription. All Canadian Pharmacies are under the jurisdiction of a provincial or territorial College of Pharmacists or similar governing body and are required to adhere to strict standards of practice. More information can be obtained by visiting the websites of the applicable College of Pharmacy.

6. All medication dispensed by Canadian Pharmacies is supplied through closely monitored Health Canada regulated supply chains, typically involving only a manufacturer, a wholesaler and a Pharmacy. 98% of these medications are shipped by the Pharmacies directly to the Patients in original, sealed manufacturer's containers. This direct distribution system ensures the highest drug pedigree and quality in North America today.

7. All medications are shipped across the border by the Pharmacy using Canada Post Xpress Post U.S.A. Service which links directly to the U.S. Priority One Mail Service to the Patient.

8. Medications requiring special storage conditions are shipped in insulated containers with cold packs and temperature indicators. If the temperature indicators show that the medication has been exposed to any extremes of temperature during transit, the Patient is asked to contact CanaRx for replacement.

9. Medications supplied by CanaRx affiliated Pharmacies to U.S. Patients are identical to the medications supplied to the Canadian market and are sourced exclusively through the same regulated Canadian supply channels. In point of fact, the CanaRx Network of Pharmacies issues over 100,000 prescriptions per day without incidence. The vast majority of these are issued to Canadians (95%) while the balance are shipped to our American clients.

The Lewin Group
3130 Fairview Park Drive
Suite 800
Falls Church, VA 22042
703.269.5500/Fax 703.269.5501
www.lewin.com

March 5, 2004

Tom Perez, Council Vice President
Montgomery County Council
100 Maryland Ave
Rockville, MD 20850

Prescription Drugs from Canada

Dear Mr. Perez:

I appreciate the opportunity to participate in the expert panel on the topic of prescription drugs from Canada at the public forum you convened on February 23, 2004.

In my opinion it is possible for Montgomery County to design a program that would enable county employees to voluntarily purchase prescription drugs from Canada, as a cost-effective option within their county-provided health insurance benefits.

This letter will summarize the elements that are crucial to ensure a safe and effective voluntary program. The elements set forth below comply with all aspects of the Canadian drug reimportation guidelines established by Congress in the recently-enacted Medicare Modernization Act ("MMA") (H.R. 1, signed by President Bush in December 2003).

Should Montgomery County choose to proceed with a voluntary program that would allow county employees to purchase prescription drugs from Canada, it is my opinion as a health care consultant who has advised many state and local jurisdictions that adhering to all of the following elements would ensure a safe and effective program that complies with all current federal guidelines:

- Only FDA-approved medications;
- Maximum 90-day supply of any given medication (to discourage re-sale, and allow for regular monitoring);
- Prohibit importation for the "first fill" of any given medication (to establish it is effective and tolerated by the patient);
- Permit importation only of county-designated maintenance medications for chronic conditions;

- The prescription must be written by the employee's local treating physician;
- The county should carefully select the approved Canadian vendor(s) according to criteria such as on-site physicians, 24 hour call center staff, and a record of compliance with all Canadian licensure laws;
- The Canadian vendor(s) must register with the Secretary of the federal Department of Health and Human Services ("HHS");
- The prescription must be for personal use by the county employee, and not for resale; and
- The prescription must be in the form of a final finished dosage that was manufactured in an establishment registered with the FDA.

Moving forward with a plan that contains these elements would enable county employees to have the option of receiving safe and effective medications in a cost-effective way.

I am aware that some individuals have questioned whether this approach to permit individual importation by county employees is legal. Clearly, the county's chief counsel and lawyers from the FDA will need to weigh in on this subject. However, as a former practicing health law attorney, I do have a view on this subject.

Prior to passage of MMA in late 2003, importation of prescription drugs was permitted under two separate sections of the federal Food, Drug and Cosmetics Act (the "Act"). One of these sections, 21 U.S.C. Section 384 ("Section 384"), addressed importation by pharmacists and wholesalers of prescription drugs for resale purposes; this importation was subject to the strict oversight and approval of the Secretary of HHS. This Section was repealed by Section 1121 of MMA, which replaced the old Section 384 with a new Section 384 (discussed below).

The other section that permits importation is 21 U.S.C. Section 381(d)(2) ("Section 381"), under which the Secretary of HHS "may authorize the importation of a drug the importation of which is [normally] prohibited . . . if the drug is required for [personal] emergency medical care." 21 U.S.C. Section 381(d)(2) was **not** repealed by MMA.

Historically, HHS has relied on Section 381 to permit individuals to import prescription drugs for their own personal use, which is why consumers historically have not been the subject of FDA enforcement actions for the importation of legal prescription drugs from Canada to treat their medical

conditions. Instead, the FDA's enforcement actions generally have been against United States pharmacists and wholesalers for violation of Section 384. Indeed, in an enforcement letter to California Deputy Attorney General Gregory Gonot dated August 25, 2003, William Hubbard of the FDA confirmed that the FDA has a policy to permit personal importation (the letter cites 21 U.S.C. Section 381(d)(1), which bars importation, without ever citing 21 U.S.C. Section 381(d)(2), which is an exception to that rule).

As noted above, there is a new Section 384 passed pursuant to MMA. Entitled "Importation of Prescription Drugs," new Section 384 governs the circumstances for importation by all entities (pharmacies, wholesalers, states, individuals, the original manufacturer, and others). It generally bars all importation without adherence to rules to be established by the Secretary of HHS. It also specifies the circumstances for waivers, to permit otherwise prohibited importation. One of these waivers involves individuals who purchase medications for their own use. In this respect, the exception found in the new Section 384 **supplements** the existing provision for personal importation found in Section 381.

In the new 21 U.S.C. Section 384(j)(3), the law states that HHS "shall by regulation grant individuals a waiver to permit individuals to import" medications from Canada, provided certain detailed conditions are met. (All of these conditions are met in the recommendations set forth above.) However, no part of the new Section 384 becomes effective until "the Secretary [of HHS] certifies to the Congress" that the overall importation rules for all affected parties are safe and cost-effective. It is worth noting that the **prohibited** importation policies found in the new Section 384 also are not effective until this certification occurs; in short, the old Section 384 has been repealed, but the new Section 384 is not yet in effect.

As a result, the legal situation as it now stands is muddy. On the one hand, an argument could be made that importation by individuals for their own use remains legal, because (a) 21 U.S.C. Section 381(d)(2) was not repealed and it permits personal importation, (b) Congress specified that the HHS "shall" grant individual waivers to allow such importation (according to safety criteria met by the proposed approach) thereby taking the option to bar such importation out of HHS's hands, (c) the provisions of 21 U.S.C. Section 381(d)(2) of the Act remain the best guidance on individual importation until the Secretary of HHS certifies new and additional criteria under 21 U.S.C. Section 384, (d) there is no presently enforcement version of 21 U.S.C. Section 384 in effect, and (e) it is not conceivable that the Secretary of HHS could thwart Congress' clear intent to permit individual waivers for personal use simply by sitting on his hands and not certifying any approach at all.

On the other hand, as the FDA asserts in its opposition to current reimportation arrangements, an argument also could be made that all individual importation for personal use may be suspended by HHS because (a) the language in 21 U.S.C. Section 381(d)(2) is permissive and the Secretary of HHS could stop permitting such importation and (b) until the Secretary certifies new guidelines under the new 21 U.S.C. Section 384, the individual waiver language is not yet in effect.

In short, in my opinion the legal issues are unresolved, and are certainly not as clear-cut as the FDA would suggest.

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Please consider this letter as a component of my testimony. Also, please let me know if there is anything else I can do to assist the county as it deliberates on this important issue.

Thank you, again, for the opportunity to participate.

Best regards,

Chuck Milligan

Charles Milligan, J.D., M.P.H.
Vice President

J. Joseph Curran, Jr.
Attorney General

Donna Hill Staton
Deputy Attorney General

Robert A. Zarnoch
Assistant Attorney General
Counsel to the General Assembly

Richard E. Israel
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The Attorney General of Maryland

Office of Counsel to the General Assembly

January 28, 2004

The Honorable Kumar P. Barve
313 Lowe House Office Building
Annapolis, Maryland 21401-1991

Dear Delegate Barve:

You have asked for advice concerning the legal consequences of a program under which the State, or one of its political subdivisions, would facilitate the importation of prescription drugs from a foreign source, such as Canada. It is my view that importation of prescription drugs from foreign sources, and thus the facilitation of such importation, is currently illegal, whether performed by the State or a political subdivision thereof. It is also possible that some liability could accrue to the State or a political subdivision from this type of activity, depending on the level of involvement of the State and the facts of the individual case. However, putting the issue of illegality aside for a moment, the State could statutorily create immunity for such a program at either the State or local level.

You have not specified the type of governmental involvement that is anticipated with respect to the importation of drugs from foreign sources, that is, whether the governmental entity would undertake importation itself, contract with an entity that imports prescription drugs, offer pharmacies in Canada as participating pharmacies with respect to pharmacy programs funded by the governmental entity, or simply provide information about the existence of entities that import drugs to residents of the United States. Obviously, the level of participation would affect the likelihood of enforcement as well as the possibility of liability. However, it is worthy of note that the Wisconsin Governor has interpreted the law to prohibit him from even posting the names of Canadian internet pharmacies on his web site.[1]

FEDERAL LAW - CURRENT

It is the position of the federal Food and Drug Administration ("FDA") that virtually any

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[1] At http://www.drugsavings.wi.gov/ Governor Jim Doyle states, "I would like to provide you with the names of those Web sites, but I can't. The Bush administration refuses to permit states to help people save money by purchasing medicine from Canada. Governor Doyle has also asked the FDA to approve the State's plan to facilitate the purchase of Canadian pharmaceuticals by providing direct links to "reputable, proven web-based companies in Canada." http://www.drugsavings.wi.gov/docview.asp?docid=29

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importation of prescription drugs from Canada or elsewhere, would violate federal law ("the FDA Act) because the drugs are generally unapproved, 21 U.S.C. § 355, labeled incorrectly, 21 U.S.C. §§ 352, 353, or dispensed without a valid prescription, 21 U.S.C. 353(b)(1). Importation of unapproved or mislabeled drugs violates 21 U.S.C. § 331(a) or (b). Importation of drugs manufactured in a state then sent abroad is limited to the original manufacturer. 21 U.S.C. § 381(d)(1). Importation by any other person violates 21 U.S.C. § 331(t). All of these violations carry criminal penalties. 21 U.S.C. § 333.

Since the FDA is the agency charged with enforcement of the federal laws governing prescription drugs, their interpretation of the statute is entitled to significant weight. Indeed, a letter from me concluding that the FDA misinterprets its own law would be of little use in the event that the FDA were to decide to bring an enforcement action against the State or one of its political subdivisions for facilitating the importation of prescription drugs. Having reviewed the matter, however, I find that I agree with their conclusions. The only court that I am aware of to look at these issues, in the context of a company that had storefronts in the United States for Canadian pharmacies, has also upheld the position of the FDA. *United States v. Rx Depot, Inc.*, 290 F.Supp.2d 1238 (N.D.Okla.2003), *stay denied, United States v. Rx Depot, Inc.*, --- F.Supp.2d ----, 2003 WL 23120030 (N.D.Okla. Nov 12, 2003).

Federal law, at 21 U.S.C. § 355 (a) provides that "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug." The approval covers not just the active ingredient, or the combination of ingredients, but also such matters as the processes, equipment and controls used during manufacture and packaging. 21 C.F.R. § 314.50. Changes in these factors, including a change in the facility or establishment used in the manufacture, processing or packaging of the drug product, requires a supplement to the approved application. 21 C.F.R. § 314.70. Thus, the mere fact that a drug has been approved for use in the United States does not mean that a version of it that is manufactured and packaged elsewhere qualifies as "approved." While it is possible for foreign manufacturers to get approval, the FDA states that most of the prescription drugs imported into the country are not approved, and that statement is supported by analysis of drug recently seized on their way into the country.[2]

The FDA Act, at 21 U.S.C. § 352, place detailed labeling requirements on drugs, including the name and place of business of the manufacturer, packer or distributor, § 352(b), an accurate statement of the quantity of the contents in terms of weight, measure or numerical count, § 352(b), the established name of the drug and of each active ingredient, § 352(e), adequate directions for use and warnings about use by persons with pathological conditions or by children if its use may be dangerous to health, and also as to unsafe dosages or methods or duration of administration, § 352(f), any applicable requirements of the U.S. Pharmacopoeia with respect to packaging, § 352(g), and the

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[2] *Sweep Shows Imported Drugs Risky, U.S. Says*, Washington Post, January 28, 2004 page A2.

medication guide if one is required, § 352(n), 21 C.F.R. § 208.20. It is apparently common that imported drugs fail to meet one or more of these requirements.

Finally, 21 U.S.C. § 381(d)(1) provides that a drug that is subject to the prescription requirement which is manufactured in a State and exported may not be brought back into the United States except by the manufacturer of the drug. Thus, re-importation of approved drugs that were manufactured in the United States under that approval and which bear all the required labeling would still be illegal for any person other than the manufacturer.

The penalty provision, 21 U.S.C. § 333(a) provides that "[a]ny person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than $1,000, or both." The law defines the term "person" to include individuals, partnerships, corporations and associations. 21 U.S.C. § 321(e). The term does not expressly include a State or other governmental entity. Nor has any case been decided that interprets the law to apply to States or their political subdivisions. A State law written in this way would not be interpreted to apply to the State. *Nationwide v. USF&G*, 314 Md. 131, 141-142 (1988). However, it has been held that the term "person" when used in federal law is broad enough to include the states and that it is not necessary to expressly mention states for them to be subject to federal law. *Case v. Bowles*, 327 U.S. 92, 99-100 (1946). As a result, it is my view that the State and its political subdivisions are bound by the requirements of federal law with respect to the importation of prescription drugs.

A showing of intent is not ordinarily required for a violation of provisions of the federal food and drug laws. *United States v. Dotterweich*, 320 U.S. 277, 281 (1943). However, the Act does require some level of involvement in the acts that constitute a violation in order for criminal liability to attach. Thus, in the corporate context, criminal penalties are applicable only to those officers or employees who had a responsible share in the furtherance of the transaction, or were in a position to prevent the violation by the exercise of foresight and vigilance. *United States v. Park*, 421 U.S. 658, 667-674 (1975). Obviously, if the State or a political subdivision were to directly undertake to import prescription drugs it would come within the criminal prohibitions of the statute., as would involved officials and employees. Contracting with an entity that imports prescription drugs in violation of the Act could also place the State or a political subdivision in a position of possible criminal liability. Whether lesser acts, such as payment of claims for prescription drugs purchased from a Canadian online pharmacy, could also lead to criminal liability is not, in my view, clearly established by current law. However, a prosecution based on such actions is not impossible.

FEDERAL LAW - NEW

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub.L. 108-173, which was signed by the President on December 8, 2003, enacted a new 21 U.S.C. § 384, directed at a possible loosening of the current prohibitions of the importation of prescription drugs. The new law would require the Secretary, "after consultation with the United States Trade

Representative and the Commissioner of Customs, [to] promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada into the United States." The regulations must require that safeguards be in place to ensure that the drugs imported under the regulations comply with the various provisions of the FDA Act with respect to approval, labeling and other matters, require that the importer comply with recordkeeping and testing requirements established by the new law, and contain any additional provisions determined by the Secretary to be appropriate as a safeguard to protect the public health or as a means to facilitate the importation of prescription drugs. The new law would also require that any establishment within Canada engaged in the distribution of a prescription drug that is imported or offered for importation into the United States register with the Secretary the name and place of business of the establishment and the name of the United States agent for the establishment. It would also permit waiver for importation by individuals for personal use on the basis of regulations or on a case-by-case basis. However, all of the provisions of the new law are contingent on certification to Congress by the Secretary that implementation will pose no additional risk to the public's health and safety and result in a significant reduction in the cost of covered products to the American consumer, and effectiveness will end if the Secretary subsequently certifies that the benefits of the program do not outweigh the detriment.

At this point there are no regulations. If such regulations were promulgated the State or a political subdivision clearly could contract with importers approved under the regulations or recommend them to its citizens. Moreover, the State or a political subdivision could form an entity that could get a license and the necessary approvals to import from approved Canadian pharmacies itself. However, I do not anticipate the promulgation of these regulations in the near future.

TORT LIABILITY

You have supplied two memoranda that discuss the potential liability of a state or local subdivision that has some involvement in the importation of drugs. The first, *State that Import or Facilitate the Importation of Foreign Pharmaceuticals Risk Lawsuits*, concentrates on the limits of common law sovereign immunity and also lists some theories under which the State or a local subdivision could be sued. The second, prepared for the Pharmaceutical Research and Manufacturers of America by Covington & Burling, discusses possible bases of liability in more detail, and concludes that "States that provide Canadian drugs directly to patients or that facilitate the provision of these drugs, though a state-sponsored pharmacy benefit plan or by other means, thus face real risks of liability." Neither focuses on specific types of government involvement or specifies what would constitute facilitation.

Without writing my own treatise on tort law, I think that is safe to conclude that there are possible State or local programs, and possible fact situations, under which the State or a political subdivision could find itself liable for injuries caused by use of imported prescription drugs. This risk would obviously be higher if the State itself engaged in importation, and lower at lesser levels

of participation. However, the State has the authority to statutorily immunize itself or its political subdivisions against suits brought on this basis if it decides to establish a program or to allow its political subdivisions to do so. Thus, while tort liability is a matter of some concern, federal criminal prohibition, in my view, presents a much more significant hurdle for such a program.

Sincerely,

Kathryn M. Rowe
Assistant Attorney General

KMR/kmr
barve02.wpd

OFFICE OF THE ATTORNEY GENERAL
State of Minnesota
ST. PAUL 55155

MIKE HATCH
ATTORNEY GENERAL

October 2, 2003

The Honorable Tim Pawlenty
Governor
130 State Capitol
75 Rev. Dr. Martin Luther King, Jr. Blvd.
St. Paul, MN 55155

The Honorable Steve Sviggum
Speaker of the House
463 State Office Building
100 Rev. Dr. Martin Luther King, Jr. Blvd.
Saint Paul, MN 55155

The Honorable John Hottinger
Senate Majority Leader
208 State Capitol
75 Rev. Dr. Martin Luther King, Jr. Blvd.
St. Paul, MN 55155

The Honorable Matt Entenza
Minority Caucus Leader
267 State Office Building
100 Rev. Dr. Martin Luther King Jr. Blvd.
Saint Paul, Minnesota 55155

The Honorable Dick Day
Senate Minority Leader
147 State Office Building
75 Rev. Dr. Martin Luther King, Jr. Blvd
St. Paul, MN 55155

Gentlemen:

The issue of prescription drug prices has been the focus of debate at both the federal and state levels for many years. Indeed, last week Governor Pawlenty noted that we shold take *extraordinary* measures to address this issue.

I enclose a copy of a report issued by this Office regarding the failure of public officials to take even *ordinary* measures to address this issue. The cost of prescription products is the fastest growing segment of the health care market. It now approaches almost 18 percent of the health care dollar. While virtually every other industrial nation has taken steps to regulate and lower the price of prescription drugs, the report shows that lawmakers have taken the opposite approach, namely to enact laws and regulations to protect the drug industry's profits and artificially increase the cost of prescription drugs. Simply put, Minnesota taxpayers are unnecessarily paying higher Minnesota and federal taxes to pay for inflated prices of prescription drugs in the Medicaid program. Minnesota taxpayers and Medicare beneficiaries, through their 20 percent deductible, also pay unnecessarily high prices for drugs covered by the federal Medicare program. Finally, Minnesota consumers who don't have prescription drug coverage

also pay unnecessarily high prices. These consumers include seniors, small business employers, sole proprietors, and the unemployed.

This year this Office drafted three bills which we believe would save tens of millions of taxpayer dollars for Minnesotans with respect to prescription drug coverage. These bills include the following provisions:

- A bill that would require drug manufacturers to accurately disclose and certify to the State Medicaid program the "average wholesale prices" ("AWPs"), and various other pricing measures, for their prescription drugs. This would enable the Medicaid program to avoid paying excessive prices for prescription drugs caused by false and inflated AWPs currently reported by drug manufacturers to drug price reporting services.

- A Minnesota False Claims Act bill that would greatly enhance the ability of the State to bring civil claims, and recover treble damages, against prescription drug manufacturers who submit false claims to the State or fraudulently try to avoid liability to the State. Such an Act, modeled after the federal False Claims Act, could be used to bring claims against drug manufacturers that defraud the State in connection with the Medicaid prescription drug rebate program. The federal False Claims Act has been used very effectively by the Department of Justice to achieve millions of dollars in recoveries from drug manufacturers for providing false information to the federal government.

- A *real* Fair Drug Pricing Act bill that would allow *all* Minnesotans the opportunity to purchase their prescription drugs at the discounted prices paid by the Medicaid program should the above bills be enacted. The bill should include an enforcement measure to ensure that drug manufacturers comply with the program and pay the supplemental rebates used to finance the discounted prices to consumers. The Fair Drug Pricing Act enacted in the last legislative session applies to a very small number of persons, has no enforcement provision, was not funded, and would expire upon the enactment of a federal Medicare drug bill that will do nothing to help Minnesotans who are not elderly.

As noted in the enclosed report, these bills either failed or were sufficiently gutted so that the bill which was enacted accomplished nothing. By adopting the above measures, this State can save tens of millions of dollars for both taxpayers and consumers. I ask that each of you commit your support for the enactment of these bills.

Governor Pawlenty has also requested that this Office review the ability of Minnesota to purchase prescription drugs from Canada, where drug prices are regulated. Under current law, the federal Food, Drug and Cosmetic Act prohibits the importation of drugs into the United States from Canada by anyone other than a drug manufacturer if the drugs were manufactured in the United States. *See* 21 U.S.C. § 381(d)(1). This provision of the law has been tempered by the FDA's long-standing practice of allowing consumers to import small amounts of prescription

drugs for their own personal use. Additionally, Section 381(d)'s prohibition may be lifted if the Secretary of Health and Human Services certifies the safety of such drugs being imported. *See* 21 U.S.C. § 384(l). To date, the Secretary has refused to do so even though drugs have been imported from Canada for years and the FDA has acknowledged that there have been *no* or negligible safety problems associated with these imported drugs. Rep. Gutknecht's bill, the Pharmaceutical Market Access Act of 2003 (H.R. 2427), passed the House this past summer and is still being debated in Congress. If passed, it would allow all citizens, not just drug manufacturers, to import drugs from Canada, and would not require the certification of the Secretary of Health and Human Services.

There is, on the other hand, no legal prohibition on the importation of drugs from Canada which are manufactured in other countries if the drugs are FDA approved, properly labeled and prescribed by a physician. *See* 21 U.S.C. §§ 353, 355. Accordingly, it is our opinion that, under current law, the State could implement a program regarding those medications, either by buying direct or by establishing a conduit through which Medicaid recipients could purchase such medication.

It should be noted, however, that rather than relying upon a Canadian regulatory system, Minnesota could adopt its own regulatory system to address the issue. Indeed, the enactment of the above three bills would be a good first step in addressing the issue. More importantly, the State of Minnesota could enter into a compact with other states willing to exercise leadership on the issue to negotiate directly with the manufacturers concerning the establishment of a formulary which would give preference to those medications that are manufactured by companies who provide a better discount. Given the fact that the States of Maine, Vermont, and Michigan have all enacted legislation related to the purchase of drugs by the state, I suspect that these three states would be sympathetic to such a compact. In addition, the Governors of Illinois and Iowa have also publicly stated their preference to purchase medication directly from Canada in order to address the issue. I suspect that they as well would be interested in joining such a compact.

Finally, several pharmaceutical companies have threatened to boycott Canadian wholesalers and pharmacies if they continue to permit the sale of pharmaceutical products to Americans. Several months ago, we initiated an investigation as to whether GlaxoSmithKline and other companies have violated antitrust laws by implementing such a boycott. GlaxoSmithKline has not fully complied with the subpoena issued by this Office and has refused to provide documents and information in the custody of its offices in Canada and its headquarters in the United Kingdom. On Monday, this Office filed a lawsuit against GlaxoSmithKline requesting an order from the court which would require GlaxoSmithKline to produce these documents and this information. When we obtain these documents and data, we will be in a better position to address the above issues.

It will be a great day for Minnesota if we can all join together in an effort to address this critical issue. The time for sound bites is over. We need results.

Very truly yours,

MIKE HATCH
Attorney General
State of Minnesota

MAH/rlh
Enclosure
AG: #924413-v1

FDA eases stance on importing medicines

The Boston Globe

FDA eases its stance on drug imports

By Jeffrey Krasner, Globe Staff, 10/24/2003

Softening a hard-line stance against the illegal importation of lower-priced prescription drugs from Canada, a senior Food and Drug Administration official said yesterday that the agency won't sue cities and states that set up plans to bring in the unapproved drugs.

"We're not considering legal action against cities or states," said William K. Hubbard, associate commissioner for policy and planning at the FDA.

The statement, made after a meeting with members of the state Senate Committee on Health Care, gives a boost to programs such as the one in Springfield, where Mayor Michael Albano has contracted with a private supplier to provide prescription drugs from Canada to city employees in hopes of saving as much as $9 million a year. Other Massachusetts cities, including Worcester, Lowell, Revere, and Pittsfield, are considering similar plans.

"This is a big admission," said state Senator Jarrett T. Barrios, Democrat of Cambridge and vice chairman of the committee, who seeks to create a state-sponsored clearinghouse of drug importation information. "Is it a green light to cities? No. But it's a yellow light that says proceed with caution. It's an acknowledgement that cities are responsibly pursuing their obligation to take care of the employees while being fiscally responsible."

Hubbard made his comments after a meeting with members of the healthcare committee. It was one of a series of meetings the FDA has had with cities and states that are considering following Springfield's lead in defiance of FDA warnings.

Hubbard said the FDA would continue its court battles against "businesses that sell commercial quantities of drugs" from overseas. The agency sent a cease-and-desist letter last month to CanaRx, the company that arranges for Canadian drugs to be shipped to Springfield. The Justice Department is awaiting a ruling after suing in Oklahoma to shut down a chain of stores that provide Canadian drugs under the names Rx Depot and Rx of Canada.

The FDA previously had indicated that it would not pursue Albano and Governor Tim Pawlenty of Minnesota, who plans to set up a website to help Minnesotans buy drugs from Canada at prices negotiated by the state, but the agency had not offered a blanket amnesty for public officials.

Despite the concession, Hubbard underscored the FDA's concerns about the safety of drugs purchased from other countries.

" `Buyer beware' isn't a system that works for drug purchasing," he said. "It's very easy to be injured by a drug."

Barrios said the safety issue is a red herring when Americans are buying drugs that were manufactured in FDA-approved facilities in the United States and handled by licensed pharmacies in Canada.

"The FDA continues to act like the proverbial ostrich with its head in the sand," he said. "It describes a world of disastrous consequences it would rather not look at."

Hubbard said the agency doesn't have the authority to write regulations necessary to implement safe importation of drugs from other countries. Such action would require additional authorization from Congress, he said.

That contention drew criticism from US Representative Marty Meehan, Democrat of Lowell, who said the Medicine Equity and Drug Safety Act of 2000 accomplished just that. But the FDA and Secretary of Health and Human Services Tommy G. Thompson haven't acted on the law, he said.

Albano, who has ignited a nationwide movement with his city drug import plan, had a laugh when told of the FDA's position. "This is a major reversal of the FDA policy, who in their own way gave me fair warning when I met with them in September," he said in a telephone interview. "I'm sure my wife will be happy when she hears the FDA won't be knocking our door down."

Montgomery College
Summary of Cost Containment Initiatives

1998 Increased College cost sharing to 75% from 77.51/2%. The change from 80% to 77.5% had been made in 1997.
Kaiser: Instituted $35 copayment for emergency room visit
Increased out-patient mental health copayments.
CIGNA Dental Care: Increased Fee Schedule

1999 The College eliminated the CIGNA Basic Plus plan. This was a traditional indemnity plan with $1000 deductible. A college contribution of $500 to a FSA was also included in this plan.

2000 Kaiser: $5.00 Copayment for office visit instituted (previously no charge).
Copayments for individual therapy $20.00/visit
Copayments for group therapy $10.00/visit
OCI: $15 Copayment instituted for urgent care facilities
CIGNA Dental Care: Increased Fee Schedule

2001 CIGNA: Instituted Passive PPO
Kaiser: RX copayment increased to $5/$15/$3 from $3/$10/$3

2002 Kaiser: RX mail order copayment changing from $3 to $5
CIGNA PPO Dental: Instituted Passive PPO
Increased annual maximum benefit to $2,000 (from $1500)

2003 CIGNA PPO: Increased individual deductible from $150 to $200
Increased RX deductible from $50 to $150
Implemented 3 Tier Drug Benefit for Mail Order Prescriptions ($20/$40/$60)
Implemented separate $250 deductible for in-patient stays.
To provide for consistency of dependent eligibility age across all of our plans, eligible dependents who are enrolled as full-time students are covered up to age 23 instead of 22.
CIGNA DPP: PCP Office Visit Copayments increased from $5 to $10
Specialist Office Visit Copayment increased from $5 to $15
Instituted 3 Tier RX Plan $10/$20/$30
Instituted 3 Tier Mail Order Plan $20/$40/$60
To provide for consistency of dependent eligibility age across all of our plans, eligible dependents who are enrolled as full-time students are covered up to age 23 instead of 22.
Kaiser: Copayments for office visits increased from $5 to $10
OCI: Copayments for office visits increased from $5 to $10
Specialist Office visit increased from $5 to $10
Instituted $300 Hospital Inpatient Copayment
Implemented 3 Tier RX Plan $10/$20/$35

LTD: Changed age from 70 to 65.

Optional Life: Added the capability for employees to have 1x, 2x, or 3x salary up to $300,000. Previously only an additional 1 x salary was allowed. This is an employee pay all benefit.

Dependent Life: Employees have the option to purchase $5,000 life insurance benefit for children and/or $25,000 life insurance benefit for spouse. This is an employee pay all benefit.

Vision Plan: Optional Vision Plan, $10 copayment for eye exam, $20 for materials. Plan design is 12/24/24. This is an employee pay all benefit.

Group Legal: Added Group Legal Benefit in Spring of 2002. This is an employee pay all benefit.

FSA's: Changed plan design to allow new employees to elect participation in FSA for dependent care only.
Increased the limit for the medical spending account from $2500 to $3000.

MCPS Summary of Cost Containment Initiatives

MCPS

2003

- New cost sharing structure for retirees to equalize contributions for under 65 and over 65 retirees.
- New co-pay structure for prescription drugs for retirees, giving them a choice between two plans and add options for cost effective coverage and reduced costs.

2002

- Competitive bidding with joint Montgomery County Agencies (MCA) of Life Insurance Program to attain cost savings.
- Competitive bidding with MCA of FSA and COBRA administration to attain lower fees and better service.
- Competitive bidding of reinsurance (stop loss coverage) to attain cost savings.

2001

- Consolidation of HMO plans – Carefirst HMO replaced George Washington and Aetna HMOs.
- Offered a Group Long Term Care Plan – Employee paid plan for all MCA.
- Competitive Bidding of Prescription Drug Program with MCA to improve discounts and rebate amounts.

2000

- Competitive bidding of HMO and Dental plans with MCA to attain cost savings through better discounts and fees.
- Prescription Drug copay changed from:

Generic/Brand	to	Generic/Brand
$2/$7		$3/$10

•Competitively bid with MCA and improved discounts for the prescription drug plan. Implemented mandatory generic program.
•Implemented discount vision plan.
•Added managed dental plan as additional dental option.
•Competitively marketed life insurance plans.

1999

- Competitively bid POS medical plan with MCA and moved to BlueCross Blue Shield for improved provider discounts and employee satisfaction.
- Competitively bid with MCA and improved discounts for the prescription drug plan.
- Unbundled prescription drug, dental and vision programs. Changed employee contribution to 10%.
- Closed indemnity plan for active employees. Moved participants to the high option POS plan.

1998

- Moved prescription drug coverage from Caremark to Kaiser for Kaiser HMO participants.
- Competitively bid indemnity plan with MCA and changed carrier to BlueCross BlueShield.

1997

- Added PPO overlay to indemnity plan to obtain provider discounts.
- Instituted disease management programs through the prescription drug program.
- Competitively bid with MCA and improved discounts for the prescription drug plan. Implemented mandatory generic program.
- Implemented discount vision plan.
- Added managed dental plan as additional dental option.
  Competitively marketed

MNCPPC Summary of Cost Containment Initiatives

PLAN YEAR	Item	PLAN	Effective Dt	CHANGE
2000	1	Nylcare PPO	1/1/2000	Dropped plan
	2	Aetna PPO	1/1/2000	Added plan
2001	1	FreeState HMO	1/1/2001	Dropped plan
	2	BlueChoice HMO	1/1/2001	Added plan
	3	Kaiser HMO	1/1/2001	Dropped plan - 37% increase
	4	Prescription - Caremark	1/1/2001	Copays increased: 2000 2001 Generic $6.00 $7.00 Brand $12.00 $15.00
	5	EE Benefit Handbook	11/1/2000	Issued the first Employee Benefit Handbook
	6	Long Term Care	7/1/2001	Added plan
2002	1	PPO	1/1/2002	Plan was dropped
	2	Prescription - Caremark	1/1/2002	Added 3rd and 4th copay tier : 2001 2002 Generic $7.00 $7.00 Formulary $15.00 $12.00 Brand $15.00 $15.00 Lifestyle 50% Added incentives to use mail: double copay at retail after 4 fills Added $5.00/ additional if generic available and not selected
	3	EE Benefit Handbook	11/1/2001	Issued revised/enhanced Employee Benefit Handbook
2003	1	Prescription - Caremark	1/1/2003	Increased copays: 2002 2003 Generic $7.00 $7.00 Formulary $12.00 $14.00 Brand $15.00 $20.00 Lifestyle 50% 50%
	2	EE Benefit Handbook	Nov-02	Issued revised/enhanced Employee Benefit Handbook
	3	All medical plans	1/1/2003	Copays increased from $5 to $10
2004	1	EE Benefit Handbook	Nov-03	Issued revised/enhanced Employee Benefit Handbook
	2	BlueChoice HMO	1/1/2004	Dropped plan - 77% increase

Recent Actions by Montgomery County Addressing Health Care Benefits, in General, and Related Costs

- Reduction of County group insurance subsidy for non-represented employees hired on or after 10/1/1994.
- Institution of a managed care point-of-service plan.
- Closing of the Indemnity Plan.
- Unbundling of group insurance benefits with opt-out options.
- Introduction of employee-pay-all benefits (optional life insurance and long term care).
- Joint procurement efforts with County agencies.
- Introduction of a dental HMO.
- Development of an integrated Benefits Administration System controlling plan eligibility and billing operations.
- Implementation of bi-annual dependent eligibility audits.
- Development of an integrated plan communication program consisting of seminars, workshops and summary plan material (including the development of the County's web based Resource Library.
- Self- insurance of the point-of-service plan and an IPA HMO (resulting in administrative cost savings).
- Retiree Cost Share initiative.

Montgomery County Council

Public Forum on Prescription Drugs from Canada

February 23, 2004
Rockville Maryland

The escalating cost of prescription drugs is a national crisis. Here in the Montgomery County Public Schools that has meant a dramatic increase in the cost of providing prescription drug coverage to the approximately 20,000 active and retired employees and their families.

Over the years the Board of Education and the unions have worked together to control costs and improve efficiencies. But the national trends are overwhelming our ability to keep the escalating costs in check. As a result, the costs to both the Board of Education, and to employees and retirees, are skyrocketing. **The premiums for our primary prescription drug plan have increased 74% over the last four years alone.**

If the costs of prescription drugs weren't increasing so much, our schools would have more money to reduce class sizes, attract and retain high performing teachers, and otherwise meet the needs of our increasingly diverse student population.

What Can Be Done to Manage Drug Costs

MCEA and the other two school unions are in negotiations with the Board of Education. The escalating cost of prescription drugs has been a central issue. The negotiating teams have been working hard to identify ways to control the sky-rocketing costs of drugs. We believe we are developing some of the most aggressive steps in the region for better managing prescription drug costs. In the process, we have learned a great deal about what the root problems are, what can be done by employers and health care consumers, and what the larger problems are that are beyond our reach.

We have learned that the current system for the marketing, sales, and distribution of prescription drugs in our country does not meet our needs. We – both Montgomery County and its employees – have no idea what we are paying for our prescription drugs. Worse still, we are paying different costs for the same drug. Employees at one agency are paying more than employees at another agency. Employees who buy at a retail pharmacy are paying more than if they buy at a mail order pharmacy. But most importantly, none of us have any idea what the drug companies are really charging us. Because of the so-called "rebates" that drug manufacturers provide to the intermediaries – the "Pharmacy Benefit Managers" –

we as consumers and purchasers don't even know the real price of the drugs we are buying.

We have learned that there are things we can and should do to better utilize our prescription drug dollars:

- We should encourage the use of generic over name brand drugs when they are available. The FDA affirms that the active ingredients in generic drugs are identical to those in the brand name drugs *(For example, a 30 day supply of 20mg of Prozac, the widely prescribed anti-depressant, costs $165. The same supply of its generic equivalent, Fluoxetine, costs only $63 – a 62% lower purchase price.)*
- We should encourage the purchasing of maintenance drugs from approved mail-order pharmacies, where they are much less expensive than at retail pharmacies. *(For example, a three months supply of 10 mg of Lipitor, the wildly successful cholesterol management drug, costs $230 retail but only $165 mail-order – a 28% lower purchase price.)*
- We should incorporate drug formularies into our prescription plans. Formularies are comprehensive, approved lists of drugs expected to meet the needs of most patients. Each formulary drug has been reviewed and approved by a health plan's panel of physicians and pharmacists based on its safety, effectiveness, quality and, all else being equal, cost. Encouraging the use of formulary drugs promotes effective treatments at the most affordable price.
- We should purchase expensive new "biotech drugs" in the most cost-efficient way, which at this point means purchasing through specialty pharmacies directly from the manufacturer and not allowing health care providers to purchase the drugs themselves while significantly marking up the costs.

Why Are Our Drug Costs Going Up So Fast?

Such steps alone will not solve the problem. Our prescription drug costs are escalating for several reasons:

1. The pharmaceutical industry is developing expensive, new life-saving drugs. For example, Refacto is a revolutionary new treatment for certain extreme hemophilia conditions. A year's treatment for a single patient has cost $360,000. The good news is that more and more other wonder drugs are in development. That's also the bad news, because at those prices, proliferation of such treatments may well break the back of our health care funding system.

2. The pharmaceutical industry has invested billions of dollars in direct marketing of drugs to patients. You can't pick up a magazine or turn on the TV without seeing the ads. Until a few years ago such direct marketing was virtually unheard of. I'm a lot more concerned about whether my doctor thinks

a certain drug is right for me than whether the company's TV ads are appealing. I'm in no position to judge the appropriateness of a new drug. That's what we have doctors and pharmacists for. There is no medical reason to spend billions of our health care dollars on direct advertising to the public – yet that is what the industry is doing with our health care dollars. It's a travesty.

3. The pharmaceutical industry also devotes untold millions of dollars courting doctors to prescribe their drugs: the golf tournaments; the free trips; the cups, notepads, and myriad other logo products they lavish on doctors. We've been told that the manufacturer of Nexium, a new drug being marketed for ulcers, has more than 12,000 sales reps out visiting doctors every day pushing their product. Yet there is not a person in the medical field we have spoken to who believes that Nexium is an improvement over pre-existing drugs. Everyone identifies Nexium as the poster child for "me-too" drugs that allow manufacturers to extend patent-protected pricing yet offer little or no clinical improvement over previous treatments.
4. According to one recent report, of the 66 new drugs that were approved in 2001, only 10 were classified as likely to be an improvement over pre-existing drugs on the market. The other 56 were "me-too" drugs. There's money to be made by marketing a new drug that is protected by patents for years to come. Not only do such drugs do little to improve the overall public health, they divert research dollars from much needed development in other areas. (PBS Frontline, 6/20/03)

Research and development of meaningful new drugs is, and should be, a high priority. **However according to a recent report issued by the Office of the Attorney General of Minnesota, between 35-37% of pharmaceutical industry revenue is spend on administration and marketing - almost three times the 13-15% of revenue the industry spends on research and development.** (www.ag.state.mn.us)

A majority of pharmaceutical research costs are already paid for by US tax credits and research grants. The Research and Experimentation Tax Credit allows drug companies to reduce their taxes on a dollar-for-dollar basis by claiming a tax credit equal to 50% of their R&D costs. As a result, the pharmaceutical industry is the least taxed industry in the country.

Additionally the federal government directly funds much of the research the leads to the development of new drugs. For example, the very successful anti-cancer drug Taxol was developed with $32 million dollars in federal funding, and then licensed to Bristol-Myers by the National Institute for Health. For the next eight years, Bristol-Myer realized more than $1 billion dollars in revenue per year from the sale of Taxol.

Another example is the other powerful anti-breast cancer drug - Tamoxifin. Tamoxifin was the product of 140 NIH sponsored clinical trials. Even though it was developed with the support of public tax-funded research in the United States, the drug costs $241 per treatment in the US compared to only $34 per treatment in Canada.

According to a recent Time Magazine Special Report, two of the largest pharmaceutical companies (Pfizer and Eli Lilly) had profit rates of 28.4% and 24.4% respectively (return on investment). The next closest companies were Intel at just 11.6% and GE at just 10.7%. The pharmaceutical industry is far and away the most profitable industry in the country. (www.time.com, 2/2/04 Special Report)

It is not a conflict to suggest that we want to continue to see research and development of new drug treatments while also affirming that we are being overcharged for the prescription drugs we buy.

What about Importation of Drugs from Canada?

MCEA believes that – properly structured – a voluntary program that allows employees, retirees and their dependents to order maintenance drugs from an approved Canadian supplier makes sense. We believe such a program would be beneficial both to our members and to the taxpayers of Montgomery County. If we can encourage the purchase of prescription drugs at lower prices, we will save the county and the school system money. Those savings can be put to better use lowering class sizes, attracting and retaining high performing teachers, and otherwise meeting the needs of our increasingly diverse student population.

There are a number of safety assurances that must be built into such a program, but which are being defined and clarified by the many states that are pursuing mail order from Canada. For example, such a plan should not support ordering from just any old internet pharmacy - such sources are highly unreliable and suspect. A plan could do what Springfield Massachusetts did, which is seek out a reputable pharmacy in Canada, inspect their operation, and contractually require certain safety protocols.

A second important safety assurance would be to require "unit of use" packaging. In Canada the pharmacy industry provides consumers with drugs in their original packaging direct from the manufacturer. If you need 30 pills, they come in a 30-pill container packaged by the manufacturer. In the US, pharmacies get their drugs in bulk form and then repackage them into consumer sized containers, creating an unnecessary opportunity for error or malpractice.

According to the Time Magazine Special Report, every year 50,000 to 100,000 people die as a result of adverse reactions from FDA-approved pharmaceutical drugs sold in America. We can all recall the recent horror story of a pharmacist who

was diluting life-sustaining medications. Yet the irony is that **neither the FDA nor the pharmaceutical industry has been able to identify any evidence of adverse impacts as a result of the widespread importation of drugs from Canada. Nor is there any evidence that the oversight of the Canadian drug system is any less stringent than it is in this country.** As one commentator has said, "If the drugs sold in Canada are so dangerous, where are all the dead Canadians?"

A comprehensive, recently completed feasibility study by the State of Illinois concluded:

- Employees and retirees can safely purchase drugs from Canada
- Pharmacy practice in Canada is equal to or superior to pharmacy practice in Illinois
- Pharmaceutical manufacturing, storage, distribution and dispensing requirements in Canada are substantially equivalent to those requirements in the US

[For a copy of the study and more information go to: www.affordabledrugs.il.gov]

It is important to realize that, to a large extent, our prescription drugs are already being imported from overseas. In 2002, $41 billion dollars worth of pharmaceutical drugs sold in the United States were manufactured overseas and imported into the country. The commonly prescribed cholesterol drug Lipitor is manufactured at a plant in Ireland. The ulcer drug Prevacid is manufactured in Japan. The other widely used cholesterol drug, Zocor, will soon be manufactured in a new plant in Singapore. Even when you buy your prescriptions at the corner pharmacy, you are probably buying imported drugs.

In our view, such a program must be offered only on a voluntary basis. If any employee or retiree is uncomfortable with this system, they must continue to be able to purchase their maintenance drugs domestically at the costs they are currently paying. A voluntary program for purchasing mail order maintenance drugs from Canada would not have to impact the current purchasing arrangements. For example, the city of Springfield Massachusetts has set up a voluntary program whereby if an employee opts to get their mail order drugs from an approved supplier in Canada the co-pays are waived and the employee only pays the shipping charge. This provides an incentive to purchase the same drug at a lower price from an approved Canadian pharmacy. Montgomery County and MCPS employees could similarly be offered an option of ordering their maintenance drugs either from a designated domestic mail order pharmacy or from a designated Canadian mail order pharmacy - with the co-pays being waived if the drug is ordered from Canada.

How much is the Potential Savings?

According to the Time Magazine Special Report, on average name-brand prescription drugs in Canada cost an estimated 40% less than the same drug when it is purchased in the United States.

For example, the most prescribed drug for MCPS employees, dependents and retirees is Lipitor, made by Pfizer. The price of a typical prescription in the US is $272 to $308 dollars. Pfizer sells the same drug in Canada for an average cost of $159 to $199 dollars - 35% to 42% less than they charge in the US. Lipitor is manufactured in Ireland and imported by Pfizer into both Canada and the US.

The MCPS drug plan spent $1.7 million dollars on Lipitor last year. If those drugs had all been purchased from a Canadian mail order pharmacy, they would have only cost $1.4 million - a savings of $300,000 on that one drug alone (18% lower purchase price). On other drugs the savings is even higher.

The potential savings to MCPS employees and to the taxpayers of Montgomery County from a voluntary Canadian mail order pharmacy is in the millions of dollars. According to work done by the agencies' benefit managers, the estimated savings for all agencies is on the order of $7 to $10 million dollars a year. The actual savings may be even higher.

MCEA conducted its own analysis of current prescription purchases in MCPS. Here's what we found (looking only at the Caremark plan data):

Total amount spent on prescription drugs:	$ 48.2 million
Total amount spent on mail order prescriptions:	$ 20.7 million
Total amount spent on the top 50 mail order prescriptions:	$ 12.8 million
Added amount spent on those same drugs purchased retail:	$ 8.5 million
Total spent on the top 50 drugs:	$ 21.3 million
Potential savings if the retail purchases were all purchased through mail order: *[note: all such purchases should not be done mail order, as most plans require the first month or two be purchased retail for safety reasons – to allow the doctor to adjust and monitor use of a new prescription]*	$ 2.3 million
Potential savings if all this purchasing occurred from Canada: *[note: based on prices from CanaRx Services, the company Reviewed and approved for use by the city of Springfield Massachusetts]*	$ 6.4 million

This projected savings is also low for several reasons:

1. This data is based only on the top 50 mail order drugs, which represent just 62% of mail order purchases. Extrapolating to 100% of mail order purchases increases the projected savings to $10.3 million.
2. This data is based on MCPS data alone. MCPS prescription costs are approximately 69% of total County Rx costs. Extrapolating to all the Montgomery County agencies increases this projected savings to $14.9 million dollars for the agencies as a whole.

There are several important caveats to these estimates:

1. This number includes the first two months of retail purchases of maintenance drugs, that should not be shifted to mail order
2. This number assumes that all the purchasing would shift to Canada. This is for illustrative purposes only. One has to build in an assumed participation rate. **A participation rate of 25% to 40% would adjust the projected savings to $3.7 to $6 million in realistic potential savings.**
3. This number does not include the 23% of participants covered by the Kaiser plan. Were those purchases included, total savings would be higher.

Conclusion

We believe it is in the interest of employees and the County to establish a voluntary prescription drug importation program. It should be limited to a single supplier who is an established, reputable vendor; who's operations are inspected; and who is required to meet specified safety protocols in a contract.

When a county agency bids a contract for prescription drug purchases, vendors from Canada should be allowed to compete. If they can offer the same products at a lower price, while meeting all the specified safety protocols, then they should be allowed to do so.

Is importation a panacea for escalating drug costs? Of course not. We need to - and are pursuing a range of other essential cost containment strategies. However we see no legitimate reason for prohibiting County and MCPS employees from purchasing the same drugs they buy now at a lower price from a legitimate vendor in Canada.

Importation from Canada may only be a short-term solution. **However if we can save our members money on their prescription plan premiums and co-pays even if only for a few years, that seems worth doing.**

If we can save county taxpayers money for a few years on the cost of providing health care to the county's workforce, that seems worth doing.

Cost Containment Opportunities

While the Task Force identified a number of opportunities/options to control rising health care costs, it should be noted that each of the County Agencies and their unions have been proactive in efforts to contain health care costs. *Exhibit #3* outlines the cost containment efforts undertaken by County agencies over the last several years. The parties should be commended for their efforts.

The Task Force focused on a variety of cost containment opportunities, including:

- Strategic use of Joint labor/management committees that can work collaboratively to address the problem of rising health care costs
- Encouraging and expanding efforts to achieve economies of scale in purchasing health care
- Improving control and oversight of pharmacy management programs
- Auditing existing programs to identify trends in utilization and pinpoint opportunities to develop interventions that target "critical cases"
- Audit claims and eligibility records to ensure the integrity of the eligibility pool
- Working with existing managed care providers to promote wellness and better utilize disease management programs

Prescription Co-pays

Prescription Plan Co-pays

Co-pays for prescription drugs are provided in the following chart. A supply of up to 90 days can be purchased through mail order for less than two retail co-payments, instead of three retail co-payments. At the retail pharmacy, the plan allows only a 34-day supply.

	RETAIL		MAILORDER		SAVINGS	
Drug Type	**Regular Co-pay**	Price if Generic is Available	**Regular Co-pay**	Price if Generic is Available	**Estimated at Mail Order**	Estimated at Mail Order
Generic	**$ 7**	$ 7	**$ 14**	$ 0	**$7**	$7
Brand- Formulary	**$ 14**	$ 19	**$ 24**	$ 34	**$18**	23
Brand, Non-Formulary	**$ 20**	$ 30	**$ 30**	$ 40	**$30**	$50
Life Style	**50%**	50%	**50%**	50%	**N/A**	N/A

Maintenance or Routine Drugs Filled At Retail

You will pay twice the retail co-pay for routine or maintenance brand drugs that are filled at the retail level more than three times. Some examples of medical conditions requiring routine or maintenance refills are: blood pressure, glaucoma, asthma, allergies, cholesterol, and diabetes. For example, if your normal co-pay at retail for a drug is $14, after the third fill you will be charged $28. The chart below shows the increased cost.

Drug Type	**Regular Co-pay**	**Co-pay After Third Fill**
Brand Formulary	$14	$28
Brand, Non-Formulary	$20	$40
Life Style	50%	100%

Brand When Generic Is Available

If either you or your doctor request a brand drug when a generic drug is available, you will be charged a higher price for the brand drug than the regular co-pay. The additional cost is $5 per script at retail and $10 per script through mail order.